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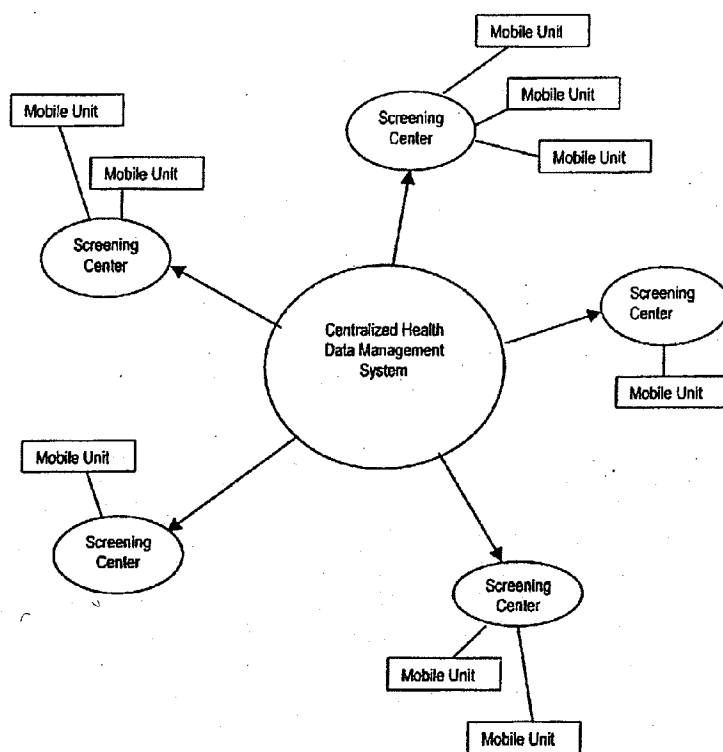
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[Continued on next page]

(54) Title: METHOD FOR CENTRALIZED HEALTH DATA MANAGEMENT



(57) Abstract: A centralized health screening and data management system is provided. Specifically, the invention includes a method, system, and computer program for maintaining a centralized health screening and data management system in communication with a plurality of screening facilities, such screening facilities including mobile units for dispatch. The screening facilities (and mobile units) provide for collecting health data and conducting tests. The data and test results are transmitted to the centralized health screening and data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis.



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DESCRIPTIONMETHOD FOR CENTRALIZED  
HEALTH DATA MANAGEMENT

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Cross-Reference to Related Applications

This application claims priority from United States provisional application, serial number 60/184,961, filed February 25, 2000, and U.S. Patent Application Serial No. *not yet assigned*, filed February 23, 2001 under Attorney Docket Number HSA-101XC1 entitled "Method, System and Computer Program for Health Data Collection, Analysis, Report  
15 Generation, and Access," the disclosures of which are incorporated herein by reference in their entirety.

Technical Field

The present invention relates to centralized health screening and data management. Specifically, the invention relates to a method, system, and computer program for maintaining  
20 a centralized health screening and data management system in communication with a plurality of screening facilities, such screening facilities also having mobile units for dispatch. The screening facilities (and mobile units) provide for collecting health data and conducting tests. The data and test results are transmitted to the centralized health screening and data management system for analysis and storage in a manner that is accessible for report generation and aggregate  
25 information analysis.

Background Art

The diseases that kill most Americans are silent thieves, leaving few clues that they are robbing individuals of good health. By the time symptoms appear, the disease is often in an advanced, sometimes fatal, stage.

Heart disease is the number one killer of adults in America. While most heart patients have no warning prior to their first heart attack, the health community now recognizes that the buildup of plaque in coronary arteries is responsible for all heart attacks. Yet, plaque does not occur overnight. It builds up over time — often as long as 10 to 20 years — before becoming severe enough to block the coronary arteries, leading to a heart attack. Traditional stress tests detect plaque in very advanced stages, when there is more than 70% blockage. Yet, 68% of heart attacks occur when blockage is less than 50%. Early detection can lead to lifestyle changes and preventive treatment, saving lives and millions of dollars in intensive care treatment.

Cancer is the number two killer of adults in our country. Early detection often makes the difference between survival and fatality. Pre-cellular changes leading to cancer often occur in the body up to 10 years prior to the formation of a tumor. While early detection strategies are common for cancers of the breast, colon and prostate, no early detection strategy for lung cancer is widely utilized. Yet, lung cancer will kill more Americans than all of the above-mentioned cancers combined. Recent studies show the use of low-dose CT Scan can detect four times the number of lung cancers as compared to traditional chest x-rays. Moreover, these cancers are six times as likely to be discovered at the earliest stage (Stage 1) when the chances for a cure are best. Yet most insurance carriers do not cover the cost of early detection screening for lung cancer. While insurance companies may authorize chest x-rays, standard x-rays do not differentiate between irregular nodules less than two centimeters in the lungs. Detection when the nodule is less than two centimeters increases lung cancer survival rates from 20% to 80%. Again, early detection and accurate risk assessment can lead to preventive treatment and positive lifestyle changes for those not yet dealing with full-blown cancer. For those with malignant tumors, early detection while tumors are small and localized greatly increases survival rates and quality of life for those survivors.

"Despite a booming economy, lack of access to health care continues to be a problem in the United States. The number of individuals without health insurance has increased from 31 million in 1987 to more than 43 million in 1997, and over 70 million lacked insurance for at least one month between 1993 and 1996" (Qtd from Family & Community Health, Betsy Smith-Campbell, Apr. 1998). For millions of uninsured Americans, regular visits to physicians and routine screening tests are considered an expensive luxury, one that is often put off until debilitating symptoms appear. According to the Florida Health Association, research by the Kaiser Family/Commonwealth Fund Study revealed two out of every five uninsured Americans did not seek needed medical care in 1997. Too often, uninsured citizens do not receive any medical attention until they arrive at the hospital emergency room. By that time, care is reactive,

not preventive and the cost is far greater and treatment comes too late to ensure optimum life quality and longevity. For instance, a 52 year-old male presents at the emergency room with pain in his chest and running down his arm, shortness of breath and dizziness. He is experiencing a heart attack, and the treatment provided to him over the ensuing 24 hours could easily run over  
5 \$20,000. Had he been screened earlier with a CAT scan for his heart, ankle brachial test and cholesterol levels, he may have avoided the heart attack with some simple, life-style changes and relatively inexpensive medication, perhaps an aspirin a day.

Even those with insurance are not guaranteed access to medical screening tests that can save lives. Insurance companies, faced with exploding costs, feel a fiscal responsibility to wait  
10 for irrefutable proof that a particular screening test saves a substantial number of lives before authorizing its use. "There are 90 million smokers in this country. If they all want a CAT lung scan every year, it would cost \$400 each - and that's a big number," said Allan Kom, chief medical officer for Blue Cross/Blue Shield Association. "We're still studying whether it would make a difference in overall survival" (qtd. in USA Today, May 25, 2000). Typically, studies  
15 determining that level of proof take 10 to 15 years and are dependent upon funding to complete. In fact, NCI is beginning a 15-year study of 100,000 clinical trial subjects. Millions of individuals will die of lung cancer awaiting the results. Consumers, many of whom are aging baby-boomers, demand more control over their health care and more immediate access to potentially life-saving health screening.

20 In addition, our society is a mobile one. Families move an average of 8 times and no longer see the same general practitioner throughout their lives. Many adults travel on business and pleasure. There is a need for quick access to medical records should an emergency arise while away from home. Millions of Americans are covered under HMOs. If their primary care or specialty physicians leave the health care network, these consumers must transfer their records  
25 to newly-assigned physicians. Often transferring records involves a fee and an extended wait time, up to several weeks.

In addition, many physicians are compelled to get authorizations for most tests and may face stringent limitations when ordering tests. Asymptomatic patients are rarely given authorizations for many potentially life-saving screening tests.

30 All of these factors point to a pressing need for a system and method that encourages wellness care through affordable health screening tests available directly to consumers, secure storage of those tests' results, and lifelong storage of health records. Further, there is a need for immediate access of those records by the client and attending physician. There is a need for custom reports generated at the time tests are performed and additional reports generated as

needed. There is a need for an educational component to the reports that explains the results, the risk assessment, resources available to learn more and, possibly, lifestyle recommendations based on the results. An added benefit of this needed system, method and computer program is the compilation of tremendous data accumulated on a largely pre-symptomatic population. Such data can be used not only to analyze medical trends but can provide proof of the effectiveness of health screenings when accompanied by full explanations of the results and educational resources to learn more about potential conditions, prevention, wellness programs and treatment options. There is a need for a business process that maximizes the productivity of every component through efficient operations streamlined procedures to insure cost effectiveness while providing highly accurate, state of the art screening results.

While a number of patents have been issued dealing with more efficient gathering and dissemination of patient information, all have been solely for use by the medical community. Thus, the consumer does not experience greater control over individual health or a reduction in the cost of necessary, possibly life-saving screening tests. In addition, the medical databases used in the current processes are primarily built with data from symptomatic patients, rather than a population more reflective of the general population.

U.S. Patent # 6,014,630 to Jeacock & Nowak is comprised of a database system of various medical procedures, practices of individual physicians, methods followed by various medical facilities and a program to select desired ones for a particular patient with the capability of modification by the doctor. The program produces a personalized patient document that explains the procedure and follow-up care. While the document produced is educational for the patient, it is limited to one particular treatment by a specific doctor. The stated purpose is to protect the physician and facility from a malpractice suit due to lack of patient knowledge or understanding. It is not intended to increase a patient's control over health or to educate the patient on preventive care techniques to enhance wellness.

U.S. Patent # 6,151,581 to Kraftson, et al is for a system and method of collecting and populating a database with physician/patient data for processing to improve practice and quality healthcare. This invention seeks to build and administer a patient management and health care management database through the use of surveys to analyze the quality of care. While this invention seeks to improve patient care through the collection of data, the data relied upon is based solely upon a variety of surveys, thus is subjective rather than objective. It is also intended for the exclusive use of the medical community, not the individual consumer.

U.S. Patent #5,796,759 to Eisenberg, et al is for a system and method for assessing the medical risk of a given outcome for a patient. The method comprises obtaining test data from a

given patient corresponding to at least one test marker for predicting the medical risk of a patient and transforming the data with the variable to produce transformed data for each of the test markers. The transformed data is compared with the mean and standard deviation values to assess the likelihood of the given outcome for the given patient and the database is updated with the actual occurrence for the given patient, whereby the determined mean and standard deviation will be adjusted. The patent does provide a basis for risk assessment that is constantly updated as data changes. However, it is limited to already symptomatic patients undergoing treatment -- in this case, maternity patients. It provides a useful tool for the medical community regarding high-risk pregnancies but cannot be used to predict overall health trends among the general population. It also does not incorporate a program to educate the consumer or inform the consumer of possible preventive care or lifestyle changes to minimize risk.

US Patent #6,101,479 to Shaw is a system and method for allocating the resources of an organization. The method includes the steps of acquiring the information required to construct a model of the organization's primary processes as viewed from the perspective of a customer. The organization's resources are then allocated to the process whose improvement will have the greatest effect on customer-based performance measures of the organization. It provides a useful tool for implementing total quality control in a manner that has the greatest impact on a customer's perception of the organization. It does not implement quality control changes that enhance the overall effectiveness of the organization, including those areas beyond the customer's purview. It does not incorporate new strategies that ultimately benefit the consumer by maximizing efficiency to maintain reasonable costs while constantly striving for additional benefits and greater accuracy.

Medical screening can locate problems early so individuals can take appropriate action. However, the results of most lab reports are incomprehensible by most consumers and are often sent directly to doctors without even informing consumers of the results. Moreover, data from such screenings is often not collected, saved, analyzed or utilized by consumers, doctors, or research organizations which could benefit from such a-symptomatic health screening data and demographics associated therewith.

Therefore, there is a need in the art for a method by which consumers can take charge of their health. There is also a need in the art for consumers to be able to receive and comprehend data from their screenings and maintain such data as a life-long health record. There is a need for such a record to be readily accessed and updated. There is also a need for the ability to collect, analyze and maintain aggregate a-symptomatic health and demographic data for scientific research which may ultimately lead to the prevention and cure for disease.

### Brief Summary of the Invention

The present invention solves the above-stated problems in the art by providing method, system, and computer program for maintaining a centralized health screening and data management system in communication with a plurality of screening facilities, such screening facilities including mobile units for dispatch. The screening facilities (and mobile units) provide for collecting health data (e.g., demographic, diagnostic, screening). The data and screening test results are transmitted to the centralized health screening and data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis.

Features of the invention can be implemented in numerous ways, including as a system, a method, a computer site, or a computer readable medium. The invention preferably relies on a communications infrastructure, for example the Internet, wherein individual interaction is possible. Several embodiments of the invention are discussed below.

As a computer system, part of the invention generally includes a database and a processor unit. The processor unit operates to receive information (health, diagnostic, and demographic) about an individual and to analyze the received information in conjunction with the statistical/known information (e.g., disease symptoms, risk factors, blood studies, screening factors) to generate customized detailed reports both for the individual and his physician. The reports may include print or electronic media.

The printed report preferably includes results from the screening with analysis and recommendations, educational information, as well as a summary for the physician.

Part or all of the data can also be sent electronically or telephonically, with devices such as fax back, and maintained on a web server for confidential access with typical browsers. The data may be accessed or sent to medical practitioners or others at the discretion and direction of the consumer. The health and demographic data collected from the screening can pre-populate a life-long health record to avoid the need for the consumer to complete long medical information forms. The data may also be transmitted and viewed by other well known techniques such as email, interactive television, and the like. The computer site is preferably viewed with a client web browser as an HTML document through a web secure server communicating with an application server having a database associated therewith.

Screening test results may be used in conjunction with carefully formatted health risk assessment questionnaires which identify increased risks associated with social habits and behaviors as well as personal health history and familial history to better assess the individual



consumer's risk and identify whether that individual may qualify to participate in and benefit from a specific clinical study. In addition, the aggregate data can be used to forecast trends and evaluate medical probabilities based on a population that more closely matches the general population. Questions in the health risk assessment should be based upon findings from prior scientific studies such as the Framingham study and/or reliable sources recognized by the medical community such as the American Heart Association and the American Cancer Association.

As a computer readable medium containing program instructions for collecting, analyzing and generating output, an embodiment of the invention includes computer readable code devices for interacting with a consumer as noted above, processing that data in conjunction with analytical information, and generating unique printed or electronic media for that consumer.

As data is collected from individual consumers, the aggregate of information may also be maintained and utilized for scientific research and studies.

The advantages of the invention are numerous. First and foremost, the invention provides for a method by which consumers can take charge of their health, allowing them to receive and comprehend data from their screenings and maintain such data as a life-long health record. Linking the screening phase to the on-line health record provides the consumer with an easier means to begin and maintain such a health record by pre-populating a majority of the data fields from data already collected during the screening process. A resulting advantage is the ability to collect, analyze and maintain aggregate a-symptomatic health, diagnostic, and demographic data for scientific research.

Other aspects and advantages of the invention will become apparent from the following detailed description taken in conjunction with the accompanying drawings, illustrating by way of example the principles of the invention.

All patents, patent applications, provisional applications, and publications referred to or cited herein, or from which a claim for benefit of priority has been made, are incorporated herein by reference in their entirety to the extent they are not inconsistent with the explicit teachings of this specification. The following patents are incorporated herein by reference: U.S. Patent Nos. 6,192,416 to *Baxter*, 6,154,726 to *Rensimer*, 6,151,581 to *Kraftson*, 6,148,297 to *Swor*, 6,144,837 to *Quy*, 6,122,351 to *Schlueter*, 6,022,315 to *Iloff*, 6,018,713 to *Coli*, 6,017,307 to *Raines*, 6,016,497 to *Suver*, 6,014,630 to *Jeacock*, 6,014,626 to *Cohen*, 6,002,915 to *Shimizu*, 5,995,937 to *DeBusk*, 5,991,731 to *Colon*, 5,991,730 to *Lubin*, 5,987,434 to *Libman*, 5,941,820 to *Zimmerman*, 5,924,074 to *Evans*, 5,890,129 to *Spurgeon*, 5,796,759 to *Eisenberg*, and 4,315,309 to *Coli*.

### Brief Description of the Drawings

In order that the manner in which the above-recited and other advantages and objects of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1A is an overall system block diagram of a preferred embodiment of the present invention.

Figure 1B is a conceptual model of the centralized health screening and data management system of a preferred embodiment of the present invention.

Figure 1C is a conceptual model of the business model which shows the organizational and consumer relationships.

Figure 2 is a system flow diagram of a preferred embodiment of the present invention.

Figure 3 is a hardware diagram of a preferred embodiment of the present invention.

Figure 4 is an entity relationship model for a preferred embodiment of the present invention.

Figures 5A - 5B are flow charts of the operation of a preferred embodiment of the present invention.

Figures 6A - 6N are process and flow diagrams of a preferred embodiment of the present invention.

Figures 7A - 7W represent a sample client report generated by a preferred embodiment of the present invention.

Figures 8A - 8H represent a sample group summary report generated by a preferred embodiment of the present invention.

Figure 9 represents one sample aggregate information report generated by a preferred embodiment of the invention.

Figures 10A - 10J represent an additional sampling of test results generated by a preferred embodiment of the present invention and available for viewing and downloading from the online lifelong health record.

It should be understood that in certain situations for reasons of computational efficiency or ease of maintenance, the ordering of the blocks of the illustrated flow charts could be

rearranged or moved inside or outside of the illustrated loops by one skilled in the art. While the present invention will be described with reference to the details of the embodiments of the invention shown in the drawing, these details are not intended to limit the scope of the invention.

#### Detailed Disclosure of the Invention

5           Reference will now be made in detail to the embodiments consistent with the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numerals used throughout the drawings refer to the same or like parts.

          The present invention solves the problems in the art by providing a method, system, and computer program for maintaining a centralized health screening and data management system  
10   in communication with a plurality of screening facilities, such screening facilities including mobile units for dispatch. The screening facilities (and mobile units) provide for collecting data and conducting tests. The data and test results are transmitted to the centralized health data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis.

15           **Figure 1A** shows an overall system block diagram of a preferred embodiment of the present invention. Central to the health screening and data management system 10 is the Health Screening Information System (HSIS) 12 which is associated with a Health Screening Association (HSA) 14 to carry out the aspects of the present invention. The HSA may consist of various clinics, mobile units, screening facilities, and the like which provide for screening of  
20   clients, and collecting screening and demographic data therefrom. The HSA 14 communicates with the HSIS 12 for processing and analyzing the data. Custom reports are generated, both at the client level in the form of a client report 16 and at a collective level in the form of a group report 17. The system data is maintained in a database 18. This data may be accessed in aggregate form by various institutions and researchers 19 for scientific research. The system also  
25   provides for user access to electronic personal health records 20 via the Internet 22 or other electronic communication means (such as fax back system).

**Figure 1B** shows the relationships between the centralized health data management system with its associated remote screening centers (SC) and their respective mobile units. The preferred embodiment provides for a plurality of remotely located screening facilities and a  
30   centralized health data management system which communicates with each of the screening facilities. The screening facilities provide for (a) gathering information from a client, the information including demographic data, health data, and risk assessment data; (b) conducting a medical screening on the client (at least one test); (c) transmitting the information and results

to the centralized health data management system; and (d) generating a report for the client according to an analysis of the results taken in conjunction with the information provided by the health data management system. The screening facilities may also be referred to herein as screening centers (SC). The screening centers usually have associated therewith at least one mobile unit to dispatch to a remote location. The mobile units are configured specifically for each location for which said mobile unit is dispatched.

The screening center provides for replication of data in the mobile unit. The data received by the mobile unit is transmitted for storage in the centralized health data management system.

A brief overview of the system will now be described with reference to the process shown in Figure 2. Initially, demographic information is collected about the consumer in step 30. Health screening tests are also conducted to collect health data in step 32. Typical screening tests include, but are not limited to, ankle brachial index, abdominal aortic aneurysm, carotid ultrasound scan, thyroid ultrasound scan, osteoporosis screening, body composition, blood and pulse pressure, oxygen saturation, hearing screening, vision screening, urine analysis, blood studies (PSA, blood count, chemistry panel, lipid panel, triglycerides and risk ratio, thyroid blood test, C-reactive protein, fibrogen, homocysteine, CEA, CA-125), hormones, CT scans. This data, as well as other relevant data, is input into the system in step 34 manually or directly from the screening devices. The health, diagnostic, and demographic data is analyzed in step 36 in conjunction with known medical/statistical data (e.g., disease symptoms, risk factors, blood studies, screening factors). The system may utilize various algorithms, real-time learning and inference technology, profiling, pattern recognition learning algorithms, neural networks, and the like in order to correlate medical/statistical information with the collected data. The necessary medical/statistical information can be gathered from various known sources or acquired and continuously updated as the database acquires information from each new consumer.

After the analysis, the next step in the process is to generate in real-time a report for the individual consumer in step 37 (or for a group of consumers, e.g., a workplace). The personalized health record reviews individualized health risks and thoroughly explains test results with follow-up recommendations. Furthermore, a personalized health assessment is provided to determine further health risks.

The present invention also utilizes the consumer's information to pre-populate a "life-long health record" accessible on the Internet (or other communication means such as, but not limited to, a fax back system) in step 38. This record stores the test results, plus medical history including allergies, medications, immunizations, insurance and physician information. From this

site, consumers can store, retrieve and analyze personal medical data about themselves and their family in a secure environment. The site allows consumers to track their own health progress and tap into a huge library of medical information. Each time a consumer is screened, the results will be added to the site. The results may also be made available to consumers by other  
5 electronic communication means such as facsimile devices, e-mail, and the like.

The aggregate of collected information is also maintained on the centralized system. This information can be accessed in step 49 and utilized by doctors and researchers to discover trends, conduct scientific research, and study a-symptomatic health data.

Figure 3 shows the preferred architecture of the present invention. The system  
10 comprises at least two networked computer processors (client component(s) for input and server component(s)) and a database(s) for storing data. The computer processors can be processors that are typically found in personal desktop computers (e.g., IBM, Dell, Macintosh), portable computers, mainframes, minicomputers, or other computing devices. Preferably in the networked client/server architecture of the present invention, a classic two or three tier client server model  
15 is utilized. Preferably, a relational database management system (RDMS), either as part of the Application Server component or as a separate component (RDB machine) provides the interface to the database.

In a preferred database-centric client/server architecture, the client application generally requests services from the application server which makes requests to the database (or the  
20 database server). The server(s) (e.g., either as part of the application server machine or a separate RDB/relational database machine) responds to the client's requests.

More specifically, the input client components are preferably complete, stand-alone personal computers offering a full range of power and features to run applications. The client component preferably operates under any operating system and includes communication means,  
25 input means, storage means, and display means. The user enters input commands into the computer processor through input means which could comprise a keyboard, mouse, or both. Alternatively, the input means could comprise any device used to transfer information or commands. The display comprises a computer monitor, television, LCD, LED, or any other means to convey information to the user. In a preferred embodiment, the user interface is a  
30 graphical user interface (GUI) written for web browser applications.

The server component(s) can be a personal computer, a minicomputer, or a mainframe and offers data management, information sharing between clients, network administration and security. The Database Server (RDBMS - Relational Database Management System) and the Application Server may be the same machine or different hosts if desired.

The present invention also envisions other computing arrangements for the client and server(s), including processing on a single machine such as a mainframe, a collection of machines, or other suitable means. The client and server machines work together to accomplish the processing of the present invention.

5       The database(s) is preferably connected to the database server component and can be any device which will hold data. For example, the database can consist of any type of magnetic or optical storing device for a computer (e.g., CDROM, internal hard drive, tape drive). The database can be located remote to the server component (with access via modem or leased line) or locally to the server component.

10       The database is preferably a relational database that is organized and accessed according to relationships between data items. The relational database would preferably consist of a plurality of tables (entities). The rows of a table represent records (collections of information about separate items) and the columns represent fields (particular attributes of a record). In its simplest conception, the relational database is a collection of data entries that "relate" to each  
15       other through at least one common field.

#### *DESCRIPTION OF PREFERRED EMBODIMENT*

The following detailed description of the preferred embodiment presents a description of certain specific embodiments to assist in understanding the claims. However, one may practice the present invention in a multitude of different embodiments as defined and covered  
20       by the claims.

For convenience, the description comprises three sections: the overview and architecture of the concentric business method and apparatus; the process used with the individual consumer and the organization; and the storage of the demographic and screening information for analysis and report generation.

#### 25       I. OVERVIEW AND ARCHITECTURE OF THE CONCENTRIC BUSINESS METHOD AND APPARATUS

Health screening, offered directly to consumers without the need of a physician's referral or an insurance company's authorization, is at the center of the concentric business method, illustrated in Figure 1C. Appropriate screening tests for this business method are those not  
30       usually offered during an annual checkup unless symptoms are clearly present. The purpose is to offer tests to a largely a-symptomatic population in order to find and correct problems while the conditions are reversible before they may become chronic or fatal. In the preferred

embodiment, screening tests are conducted with FDA approved, cutting-edge technology by experienced health professionals supervised by board-certified physicians. Tests may be designed to increase the comfort level of the client by ensuring as little discomfort as possible through painless non-invasive procedures that do not require disrobing to complete. Clients' comfort levels may further be raised through personal and immediate attention without the typical long waiting periods many people experience when completing physician ordered tests in other environments. In the preferred embodiment, patients are treated like preferred consumers whose time is valuable and right to know is paramount. Whenever tests do not require review by a certified physician, test results may be available immediately.

The health screening facility surrounds the consumer in the center of the concentric business method, acting as both a buffer zone and a facilitator between the consumer and the community at large; including the medical research community, the consumer's employer or potential employer and health care providers. The facility protects the consumer's privacy through careful storage in a database of screening test results and data, allowing access to the consumer's records only under the direction of the consumer and only in an anonymous manner that totally protects the consumer from any chance of personal information becoming public. At the same time, the facility matches helpful information, educational and clinical opportunities to the consumer, as long as the consumer permits the facility to do so, acting as a bridge between the medical community and the consumer. For instance, if the anonymous screening and assessment test results reveal a close fit for a clinical study, the facility provides information on the study to the consumer. If the consumer expresses interest in pursuing the opportunity, the facility would release the consumer's contact information to the researchers. Thus, the consumer experience has the optimum opportunity to benefit from cutting-edge medical advancements without endangering personal privacy.

The health screening facility is responsible for the process of storing test and health risk assessment results, Figure 1C. At the center of the architecture for this layer is a computer with sufficient space to create and maintain space required for storage of the demographic, diagnostic and screening data, multiple informational tables and educational information. Test results and pertinent information from the tables may be included in a client test result report as well as a variety of other reports issued upon request. A medical database is created on the host computer. The medical database is comprised of two databases: the primary, relational database and a subsidiary, hierarchical database that contains all the tables of information, including but not limited to normal ranges of test results and risk assessments. Accurate tables populated with the most current information available from the most reliable medical resources are essential. The

subsidiary database is more static and information is automatically pulled from there to populate specific fields in the reports generated in the primary database which operates in real-time.

In the preferred embodiment, the database script is written in SQL and the source code in Visual Basic, but they may be written in any combination of computer languages capable of  
5 creating both hierarchical and relational, object-oriented databases with communication embedded between them. Report software may also be utilized. In the preferred embodiment, Seagate Crystal Reports and Microsoft Excel are utilized, but any database management tool or system that is SQL compatible may be used including, but not limited to, Oracle and DB2. When  
10 information is pulled from SQL, it is put into Crystal Report for report generation and information analysis.

Additional workstations equipped with computers and printers may be used at point of service to enter demographic and screening data as well as generate appropriate reports, if desired. In the preferred embodiment, each computer at a permanent location has a shortcut on the desktop to the application that has a connection to the relational database. Computers in  
15 remote mobile units are preferably not connected to the primary database. Instead they are connected to a mobile server and use a merge replication to ensure autonomous function without a direct connection to the primary database. A production server is used for the permanent workstations.

In the preferred embodiment, mobile units may be transported any place in the world  
20 because each unit contains a mobile server and medical testing equipment, shipped in carefully-fitted rugged containers for safety and portability. To ensure efficiency, the mobile units would be transported from the permanent screening site closest to the health event. The preferred embodiment of this business model could include multiple health screening sites and one centrally located corporate headquarters, as illustrated in Figure 1B. The corporate  
25 headquarters would be the hub, providing the centralized health data management system which supports the screening facilities, which are the spokes in this analogy. The centralization of services in the health data management system, such as information technology, marketing, storage, analysis, and the like, provides maximum efficiency and cost containment, keeping the cost of health screening as reasonable as possible and therefore, affordable to a greater number  
30 of consumers.

Mobile units, located at the spokes (screening facilities) may be re-configured as the health event dictates so that only the medical testing equipment, server and portable workstations needed for that event are moved. Transportation may be by ground, air or sea as the metal containers meet all shipping requirements. Replication of data in mobile units ensures the data



can be accurately entered wherever the health event may be located. When merged, the data becomes part of the information in the relational database and it signals the subsidiary database, just as data entered from permanent locations does.

The mobile units may communicate with the HSIS in a number of ways. For example,  
5 there may be provided a method of propagating data throughout a computer system having mobile computers, and a computer server device at a fixed site (e.g., closest screening center), the method comprising providing relevant data at the computer server device to be transferred to the mobile computers, making a data exchange connection between a mobile computer and the computer server device when a mobile computer visits the site, providing software  
10 authorization checking when the data exchange connection is made to determine if the mobile computer is an authorized computer, conducting software checking to determine if relevant data resident in the computer server device is more recent than the relevant data in the mobile computer, invoking further software to transfer the relevant data from the computer server device to the computer if it is more recent than the relevant data in the mobile computer, and if the  
15 relevant data in the mobile computer is more recent than the relevant data in the computer server device, invoking further software to transfer the relevant data from the mobile computer to the computer server device, and repeating the process with further mobile computers when they visit the site whereby the relevant data can be propagated.

The subsidiary, hierarchical database is essentially a lookup database. In the preferred  
20 embodiment, List Manager is used. Hierarchical logic is incorporated in the program. The tables are composed of tasks, categories, tests, expected results, and the format of the expected results. Each test attribute has a unique identification number (ID#) which corresponds to the event in the List Manager.

Since the medical database contains consumers' health and information, strong security  
25 in the form of a firewall is used. In the preferred embodiment, further security protection is incorporated. For example, each client may be assigned an unique 14-digit identification number, rather than a more traceable identifier such as a Social Security number.

An Internet or business network (ITP connection) is used to support the database internally and an Internet web site accessible by all with several degrees of secured access is  
30 used to allow immediate, remote access to records and relevant educational information for both clients and physicians.

Because screening tests are offered directly to the consumer, educating the consumer to the availability and importance of early detection health screening is important. In the preferred embodiment, increasing consumer awareness is accomplished through a variety of methods,

including participation in community-sponsored health fairs, marketing strategies and educational as well as scheduling information available on the web site which hosts the life-long health record, an example of which is shown in Figures 10A - 10J.

## II. PROCESS USED WITH INDIVIDUAL CONSUMERS AND ORGANIZATIONS

5       **Figure 5A** is a flowchart showing the process for the individual with sub chart, **Figure 5B**, showing the process when an organization is sponsoring or hosting the health-screening event. Individual consumers call to obtain information and make an appointment. The individual's demographic data is entered into the database along with the time, date and location of appointment and the tests or test package desired. The cost is automatically figured and the  
10       appointment maker goes over the cost and any preparation needed, such as four hours of fasting for the glucose test. An alternative scheduling method could be offered at the web site wherein consumers could schedule appointments for health screening tests through a secured connection over the Internet.

**Figure 5B** starts with the booking of the event for the organization. All pertinent  
15       information is entered into the database, including time, date, location, tests or packages offered. Organizations can choose one package for each member or employee at a discounted fee or may choose to let their members or employees choose the tests desired. Responsibility for payment is also noted in the database as some business organizations fully cover the costs of the program for their employees under wellness plans. Health screenings can also be booked as events when  
20       a public organization, such as a local school or health department, wants to hold open house health fairs. Generally, no advance appointments may be needed when public organizations host health fairs. Types of tests given at health fairs may be limited to basics such as blood pressure, cholesterol readings, and vision/hearing screenings. Often, cost is nominal or free. In those cases, the event is entered into the database, so that data can be entered and tracked on the day of the  
25       event.

      Upon arrival at the location, both individuals and members of organizations are asked to sign consent forms. The consent forms preferably consist of four sections:

- (1) consent to take the tests;
- (2) consent to have the results posted on a secured, privacy-protected life-long health  
30       record accessible with a web browser;
- (3) consent to receive information in electronic and/or printed formats; and
- (4) consent to let their data be anonymously used in a statistical database to help forecast health trends and assess risk factors among a largely a-symptomatic population and to

be informed of clinical trials and experimental treatments that may pertain to them, according to their test results.

In the preferred embodiment, all four consents would be given, but clients are given the tests as long as they sign the first portion of the consent form. Information including which  
5 consents were given and the date signed is entered into the database prior to any tests being performed. As a safeguard, the program is designed to prevent any further action being taken until the consent information is entered. At the point the consent information is entered, the computer automatically assigns a unique identifier to the client. The use of this identifier increases security. Many consumers are concerned that insurance carriers or employers may use  
10 information about health risks to deny coverage or employment opportunities. Avoiding the use of easily traceable numbers, such as social security numbers, helps maintain the consumer's right to privacy. Each time a client comes in, the consent forms are reviewed, and any changes noted.

The client is taken to the testing area where the procedure is explained in detail by the technician. The test is performed and the data is entered into the database in the most error-free  
15 way possible. In the preferred embodiment, the data is not entered by data entry personnel but by direct entry from the equipment or a smart card-type device. To further increase accuracy, additional accuracy checks may be instituted on a regular basis. For instance, another member of the facility staff not involved with the consumer's screening test may review the test results to certify that the results were entered correctly. In the preferred embodiment, two additional  
20 accuracy checks are routinely made to ensure the data is correct to the greatest degree possible. Such direct entry and accuracy checks avoid the risk of human error, such as reversing digits, and ensures a higher degree of accuracy.

Once all tests are completed, the client may be given a report, an example of which is shown in Figures 7A - 7W. The printed report preferably includes results from the screening  
25 with analysis and recommendations well as a summary for the physician. For example, the suggestion to eat a low fat diet and increase exercise could be passed on from the American Heart Association to a client with high body fat content and high cholesterol levels. In the preferred embodiment, only suggestions and recommendations widely accepted by the medical community and supported by well-respected authorities in the field, such as the American  
30 Diabetes Association, are made to consumers. However, under circumstances in which this invention is practiced by the consumer's personal physician, the preferred embodiment could include additional recommendations. The only test results that could not be included on the immediate report are those requiring medical review, such as the CT lung scan which needs to

be reviewed by a radiologist. The client may be informed those results will be sent within a few days.

For events hosted by businesses and organizations, an additional report may be generated which employers may use to design effective wellness programs for their employees, an example of which is shown in Figures 8A - 8H.

Part or all of the data can be sent electronically or telephonically, with devices such as fax back, and maintained on a web server for confidential access with typical browsers. The health and demographic data collected from the screening can pre-populate a life-long health record, which is an electronic health record which may be maintained and updated for a consumer. The life-long health record provides for viewing of the screening results electronically and for downloading for printing -- providing a complete report of the screening tests and health risk assessment results (an example of such a report is shown in Figures 10A - 10J). The life-long health record also provides for input screens for the consumer to add helpful information to complete the health history, from records of immunizations, medications previously or currently taken, and physician's contact information to search screens that allow the consumer to search for more information on a specific condition or to locate a new health care giver.

The data may also be viewed by other well-known techniques such as email, interactive television, and the like. The computer site is preferably viewed with a client web browser as an HTML document through a web secure server communicating with an application server having a database therewith. In the preferred embodiment, the client is assigned a password to use on the Internet web site which stores the test results, downloaded directly from the database. This allows immediate, secured access to the records by the consumer and appropriate physician. Additional reports can be printed and information can be updated to include other health records; however, no changes can be made to the test results. Other educational information can also be found on the web site and links are provided to additional helpful sites. Each time a client returns for additional testing, the database and lifelong health record on the web site are automatically updated through the database.

The web site may also be used by consumers who have not had any screening tests performed at the facility or mobile site. Health-related educational information, facility information, interactive quizzes and activities as well as links to other helpful health web sites may be incorporated. The web site may generate additional clients for the health screening tests and increase awareness of the need for early detection, thus generating more health screening

tests. This in turn increases the pool of statistics to be used for scientific analysis and appropriate candidates for clinical trials.

### III. STORAGE OF THE DEMOGRAPHIC AND SCREENING INFORMATION FOR ANALYSIS AND REPORT GENERATION

5       The database has three essential purposes. It stores individual data for consumers to allow them to have greater control over their health and well-being as well as greater, immediate access to their health records. Figures 7A - 7W is an example of a client report including a detachable section for the client's physician. The report gives comprehensive explanations of each test offered and charts which clearly show the normal ranges for each test. Preformatted and  
10       scripted, the report takes only a few minutes to print as the database pulls the information needed from List Manager and the results from the tests taken.

      Figures 8A - 8H illustrate an example of a printed Employer Summary Report, which could be issued after a health event held for a company. The medical facility operating this system, method and program may choose to give such a report to the organization, along with  
15       individual reports given only to the individual participants. The employer summary report provides documentation on the overall fitness of the staff, without releasing any private information. It explains each test given, including the possible reasons for the condition and the normal ranges. This example breaks down the overall results of the tests by gender in chart format, showing percentages of those within specific ranges. Recommendations for further  
20       medical care or lifestyle changes are also included. Such a report, in print or electronic media, can help the organization develop a wellness program that will benefit more of their employees because it pinpoints the greatest needs. In turn, healthier employees experience less absenteeism and the organization's productivity increases.

      As screening data is collected from individual consumers, the aggregate of information  
25       may also be maintained for scientific research. This invention amasses critical data on a largely a-symptomatic population by storing all the medical and demographic information without any personal identifiers. That information can help the medical community develop trend data and risk assessments on a far wider population than has generally been available before. Up until now, most databases have information on patients who already have symptoms, full-fledged  
30       diseases, or passed away. In some cases, determinations of risk are based on a population that is largely deceased. Yet, we all know that people are living longer and healthier lives today. At the same time, some risk factors have increased. For instance, the United States has a greater percentage of obese people than at any other time in the last century. Moreover, the fastest

growing segment of obesity is found in the under 21 population. If new ways of combating obesity are not discovered through scientific research and clinical trials, the United States could be looking at far greater instances of obesity-related disease in the next 20-40 years. Having more current information available to the medical community can translate into tremendous leaps forward in preventive care and early intervention.

Reports can be generated that detail risks according to location, age, gender and specific medical factors. Medical personnel can use that information to populate clinical trials with a cross-section of people at increased risk. To date, most clinical trials for preventive care rely upon advertising to the public in hopes of getting responses from those who are at greater risk. For instance, a large Tomaxofen study advertised for women who have had some family history of breast cancer. Researchers were forced to rely upon the accuracy of the women's memories, and, in some cases, stories repeated by family members but not experienced by the women, themselves, when choosing candidates for the study. With this invention, researchers will be able to choose candidates whose DNA contains the specific gene related to increased risk of breast cancer.

A clinical trial based upon known evidence of risk factors could prove invaluable and produce more accurate results. For example, a clinical trial could use the more concrete criteria of at least 30% but not more than 45% calcified plaque in the coronary arteries to test medication for the prevention of heart attack. The database would generate a report based on the health screening of those participants who authorized information be released for clinical trials, and those people could be contacted directly by the medical personnel running the trial.

In addition, other reports can be generated, from those that show the source of business for the health-screening center (Figure 9) to those that delineate overall results from all participants by test. Results of these reports can be used to pinpoint areas or groups of people who may need further education about the importance of early detection and preventive care in addition to business forecasting. Custom reports can list the normal, abnormal and total for each test for a specific period of time or the abnormal result percentage for each test. This data can be used for trending forecasts and immediate risk assessments.

Accordingly, the advantages of the present invention are numerous. For example, the knowledge that consumers can take part in comprehensive health screening without incurring penalties from their insurance companies or employers frees consumers to become better informed and armed to fight off disease through early intervention. Viewing and fully understanding concrete test results often provides the needed catalyst to seek treatment and/or make positive lifestyle changes. Being able to access the reports immediately through the

Internet provides a greater measure of security while traveling, if a medical emergency should arise. Immediate accessibility to the client's lifelong health record also makes changing doctors or seeking second opinions easier and faster than waiting for medical records from a physician's office. Automatic updating of the records every time health screening tests are taken provides  
5 a complete, convenient record that may span most of the consumer's lifetime, creating a more thorough record than is generally available. The additional information the consumer may add, such as the results of physician ordered tests or a record of medicine taken and any adverse effects could prove invaluable.

Although the invention has been described with respect to a health screening model, it  
10 is contemplated that other industries which utilize a centralized data management system with screening facilities may come within the scope of this invention as applicable.

Based on the foregoing specification, the invention may be implemented using computer programming or engineering techniques including computer software, firmware, hardware or any combination or subset thereof. Any such resulting program, having computer-readable code  
15 means, may be embodied or provided within one or more computer-readable media, thereby making a computer program product, i.e., an article of manufacture, according to the invention. The computer readable media may be, for instance, a fixed (hard) drive, diskette, optical disk, magnetic tape, semiconductor memory such as read-only memory (ROM), etc., or any transmitting/receiving medium such as the Internet or other communication network or link. The  
20 article of manufacture containing the computer code may be made and/or used by executing the code directly from one medium, by copying the code from one medium to another medium, or by transmitting the code over a network.

One skilled in the art of computer science will easily be able to combine the software created as described with appropriate general purpose or special purpose computer hardware to  
25 create a computer system or computer sub-system embodying the method of the invention. An apparatus for making, using or selling the invention may be one or more processing systems including, but not limited to, a central processing unit (CPU), memory, storage devices, communication links and devices, servers, I/O devices, or any sub-components of one or more processing systems, including software, firmware, hardware or any combination or subset  
30 thereof, which embody the invention. User input may be received from the keyboard, mouse, pen, voice, touch screen, or any other means by which a human can input data into a computer, including through other programs such as application programs.

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be

suggested to persons skilled in the art and are to be included within the spirit and purview of the claims.



## CLAIMS

What is claimed is:

- 1           1. A method for centralized health screening and data management comprising:
  - 2           a) providing a plurality of remotely located screening units;
  - 3           b) providing a centralized health data management system; and
  - 4           c) enabling data communication between the centralized health data management system
  - 5           and each of the screening units, wherein each of the screening units provides for:
    - 6           i) gathering information from a client, said information comprising demographic data,
    - 7           health data, and risk assessment data;
    - 8           ii) conducting a medical screening on the client, wherein said screening comprises at
    - 9           least one test;
    - 10           iii) transmitting said information and results from said at least one test to said centralized
    - 11           health data management system; and
    - 12           iv) generating a report for the client according to an analysis of the results taken in
    - 13           conjunction with said information provided by said health data management system.
- 1           2. The method of claim 1 wherein said remotely located screening units comprise
- 2           screening centers.
- 1           3. The method of claim 2 wherein said screening centers comprise at least one mobile
- 2           unit associated therewith, wherein said screening center dispatches said mobile unit to a remote
- 3           location.
- 1           4. The method of claim 3 wherein said mobile units are configured specifically for each
- 2           location for which said mobile unit is dispatched.
- 1           5. The method of claim 3 wherein said screening center provides for replication of data
- 2           in said mobile unit.

1           6. The method of claim 3 wherein data received by said mobile unit is transmitted for  
2 storage in said centralized health data management system.

1           7. The method of claim 1 wherein risk assessment data is gathered from the client by  
2 utilizing a predetermined series of questions designed to elicit data associated with a plurality  
3 of risk factors.

1           8. The method of claim 1 wherein the step of conducting medical screening on the client  
2 comprises:

3           assigning a unique client identifier to the client;  
4           assigning a unique screening identifier for said medical screening;  
5           associating said client identifier with said screening identifier;  
6           recording start time of said screening;  
7           conducting at least one test; and  
8           recording end time of said screening.

1           9. The method of claim 8 further comprising:

2           storing said information and results from said at least one test in a database associated  
3 with said centralized health data management system;

4           associating a unique test identifier for each test taken by the client with said client  
5 identifier; and

6           assigning a unique results identifier, said results identifier associated with said client  
7 identifier.

1           10. The method of claim 7 wherein said analysis of the results taken in conjunction with  
2 said information provided by said health data management system comprises, for each of a  
3 plurality of risk factors,

4           a) assigning unique identifier for each risk factor,  
5           b) analyzing said risk assessment data; and  
6           c) determining a risk indication for the client for each risk factor.

1           11. The method of claim 10 wherein said risk indication is a positive or negative  
2     indicator.

1           12. The method of claim 10 further comprising considering a client's age category in  
2     determining said risk indication.

1           13. The method of claim 10 further comprising considering a client's gender in  
2     determining said risk indication.

1           14. The method of claim 10 further comprising considering a client's race in determining  
2     said risk indication.

1           15. The method of claim 1 wherein the report generated for the client according to said  
2     analysis comprises:

3           a screening summary comprising test name, client results, and normal ranges;  
4           a detailed report comprising educational information for each of said tests conducted  
5     during client screening, said educational information comprising test name, client results, normal  
6     ranges, associated health risks, recommendations, and test protocols; and  
7           a physician's report comprising test name, client results, and normal ranges.

1           16. The method of claim 1 further comprising pre-populating an electronic health record  
2     for remote access by the client.

1           17. The method of claim 16 wherein the step of populating an electronic health record  
2     for remote access by the client comprises:

3           establishing a remotely accessible secure file for said client;  
4           storing demographic information collected from said client;  
5           storing test results for said client for each screening;  
6           allowing client to update file with additional data;  
7           allowing client to control access to data by others.

1           18. The method of claim 1 wherein said steps are performed for each of a plurality of  
2 clients in an organization wherein said organization has assigned thereto a unique organization  
3 identifier and said organization identifier is associated with each client who is a member of the  
4 organization.

1           19. The method of claim 18 further comprising assigning a unique department identifier  
2 for each department in said organization wherein said department identifier is associated with  
3 each client who is a member of the department.

1           20. The method of claim 18 further comprising generating an organization report, said  
2 organization report comprising:  
3 results summary showing percent of organization at risk for at least one category of  
4 health risks;  
5 participation percentages by department, age groups, gender, and sex; and  
6 detailed reports showing levels of risk by percentage of clients in each category.

1           21. The method of claim 1 further comprising combining the results of a plurality of  
2 clients in a database of said centralized health management system to provide aggregate  
3 information and providing access to said aggregate information.

1           22. A system for centralized health data management, comprising:  
2 a centralized health data management system;  
3 a plurality of remotely located screening units, each of said screening units comprising:  
4 (a) input means for gathering information from a client, said information  
5 comprising demographic data, health data, and risk assessment data;  
6 (b) screening devices for administering a medical screening on the client,  
7 wherein said screening comprises at least one test;  
8 (c) communication means for transmitting said information and results from said  
9 at least one test to said centralized health data management system; and  
10 (d) output means for generating a report for the client according to an analysis  
11 of the results taken in conjunction with said information provided by said health data  
12 management system.

1           23. The system of claim 22 wherein said centralized health data management system  
2 comprises processing means for analyzing results in conjunction with risk factors associated with  
3 the client and pre-populating an electronic health record for remote access by the client.

1           24. In a centralized health data management system having a plurality of remote  
2 screening units communicating therewith, a computer readable media containing program  
3 instructions for outputting data from a computer system, the data being obtained from tables in  
4 a database associated with the centralized health data management system, said computer  
5 readable media comprising:

6           first computer program code in each of said remote screening units for gathering  
7 information from a client, said information comprising demographic data, health data, and risk  
8 assessment data;

9           second computer program code in each of said remote screening units for recording the  
10 results of a medical screening administered to the client, wherein said screening comprises at  
11 least one test;

12          third computer program code in each of said remote screening units for transmitting said  
13 information and results to a centralized health data management system;

14          fourth computer program code in said centralized health data management system for  
15 analyzing results in conjunction with risk factors associated with the client; and

16          fifth computer program code for generating a report for the client according to an  
17 analysis of the results taken in conjunction with said information.

1           25. A centralized system for storing and retrieving health data from a plurality of remote  
2 screening units comprising:

3           a relational database for storing data comprising a plurality of interrelated tables wherein  
4 each table comprises an attribute having a common domain with an attribute of at least one other  
5 table in the database; and

6           means for collecting and storing demographic information from a client in said database,  
7 the client having assigned thereto a unique client identifier;

8           means for conducting a medical screening on the client at each of said remote screening  
9 units, wherein said screening comprises at least one test;

10          means for storing results from said at least one test in said database;

11          means for analyzing results in conjunction with risk factors associated with the client;

12          and

13 means for generating a report for the client according to said analysis on the basis of the  
14 data stored in the relational database.

1 26. The system of claim 25 further comprising means for pre-populating an electronic  
2 health record for remote access by the client.

1 27. The system of claim 25 further comprising a plurality of dispatchable mobile units  
2 associated with said remote screening units, said mobile units selectively configured to provide  
3 means for collecting and storing demographic information from a client in said database and  
4 means for conducting a medical screening on the client.  
5

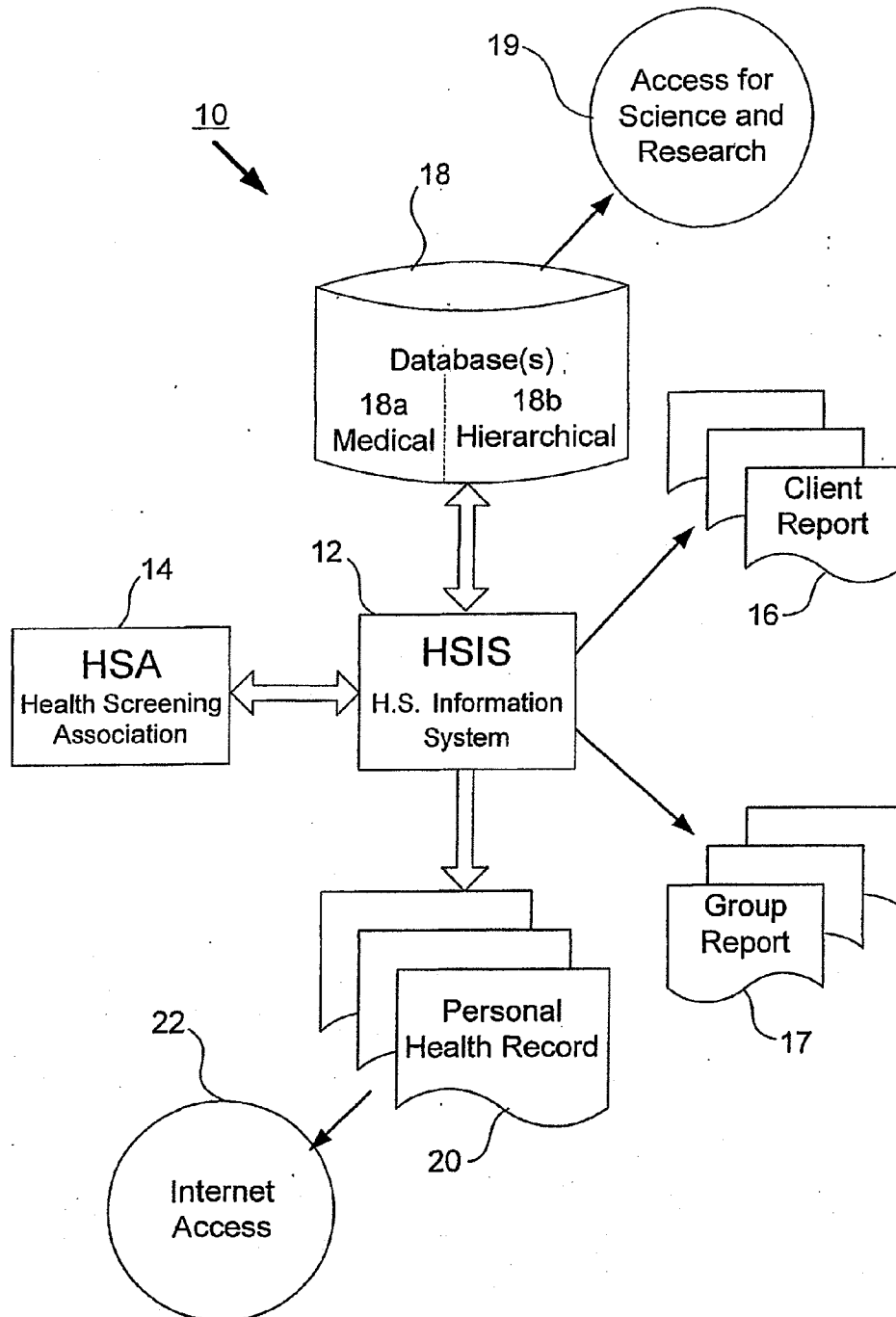
**Figure 1A**

Figure 1B

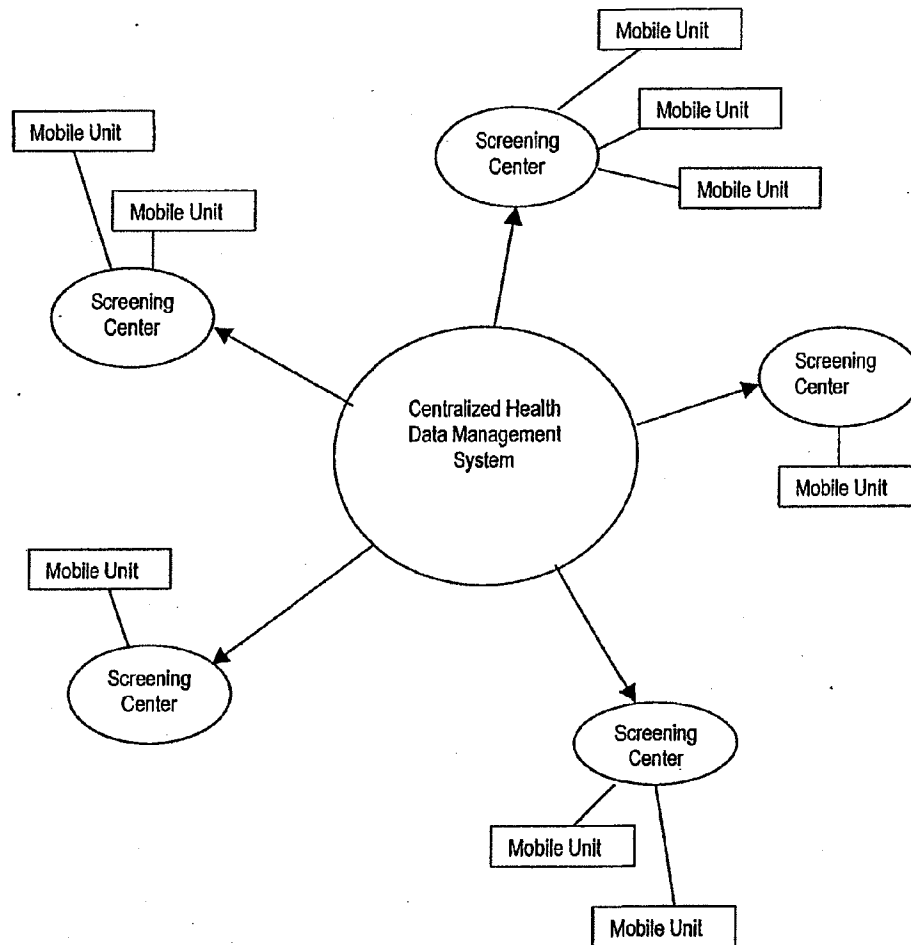
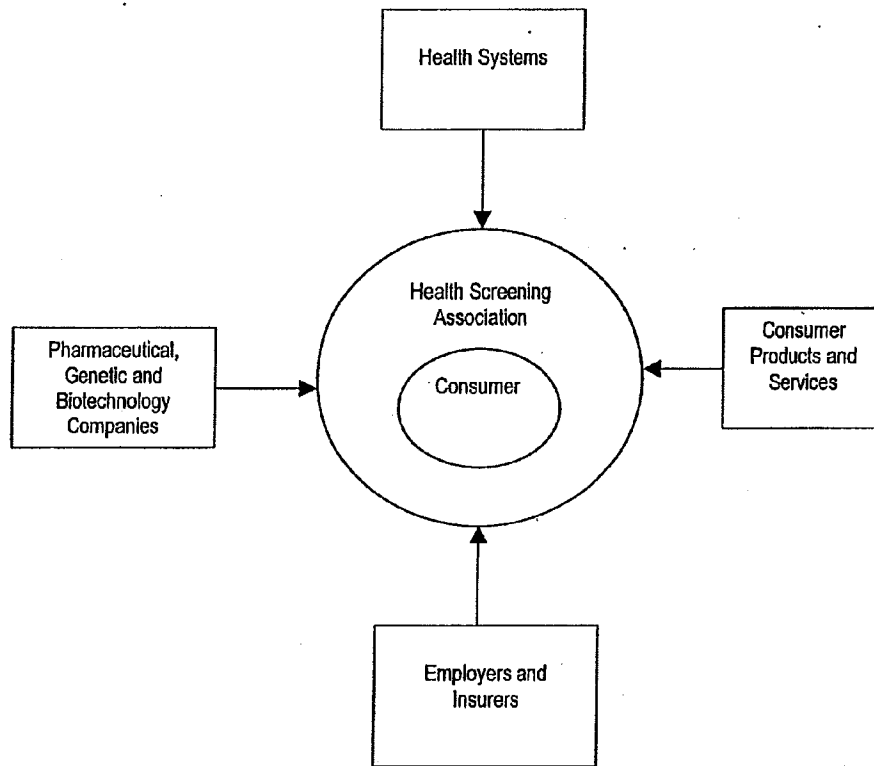




Figure 1C



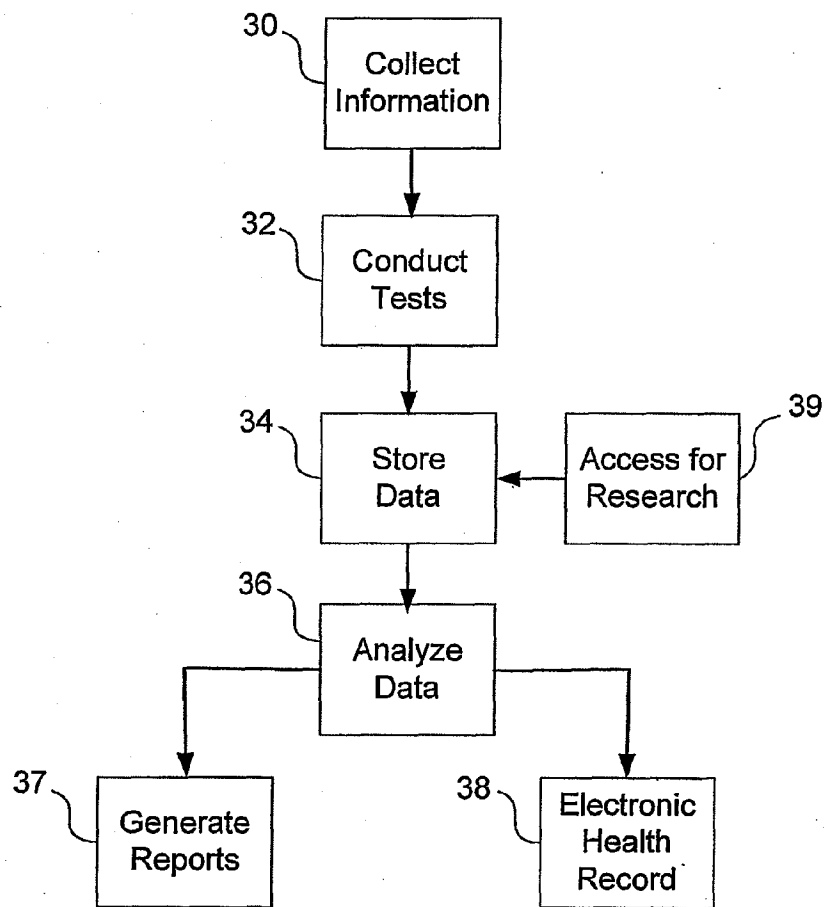


FIG. 2

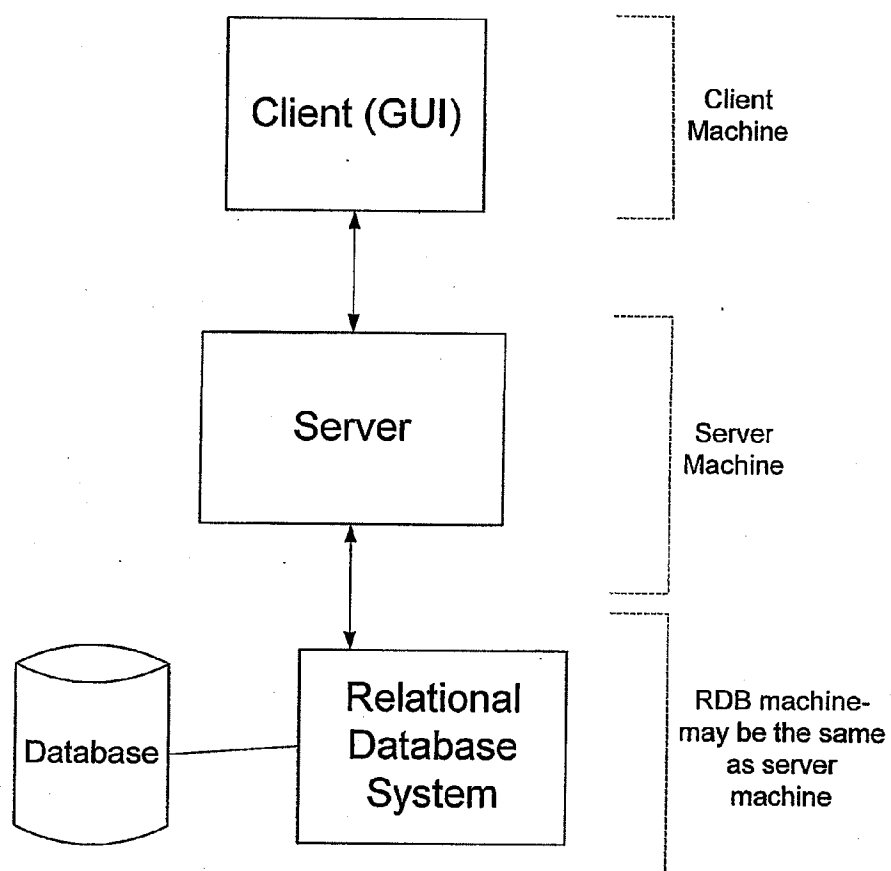


FIG. 3

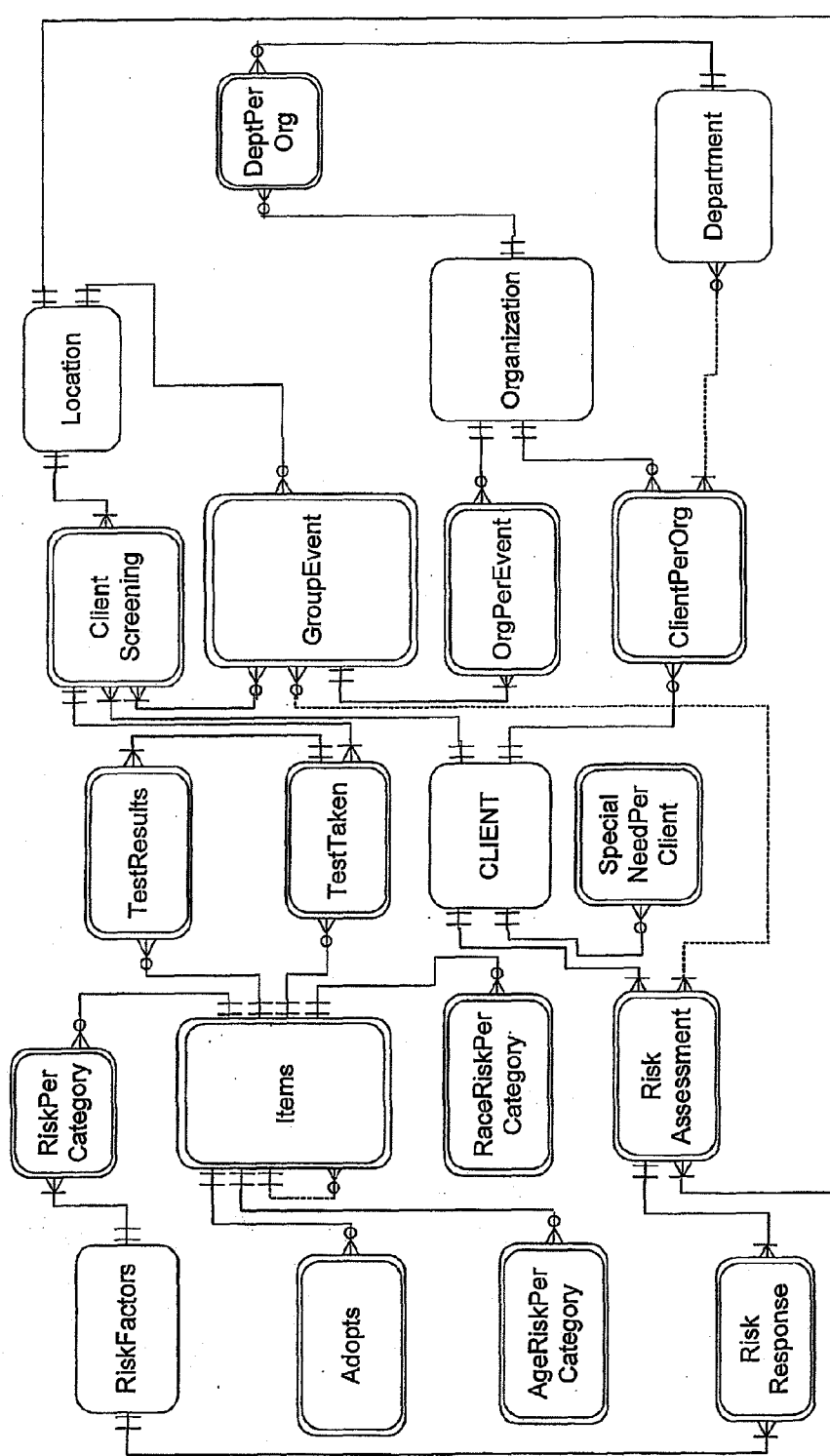


FIG. 4

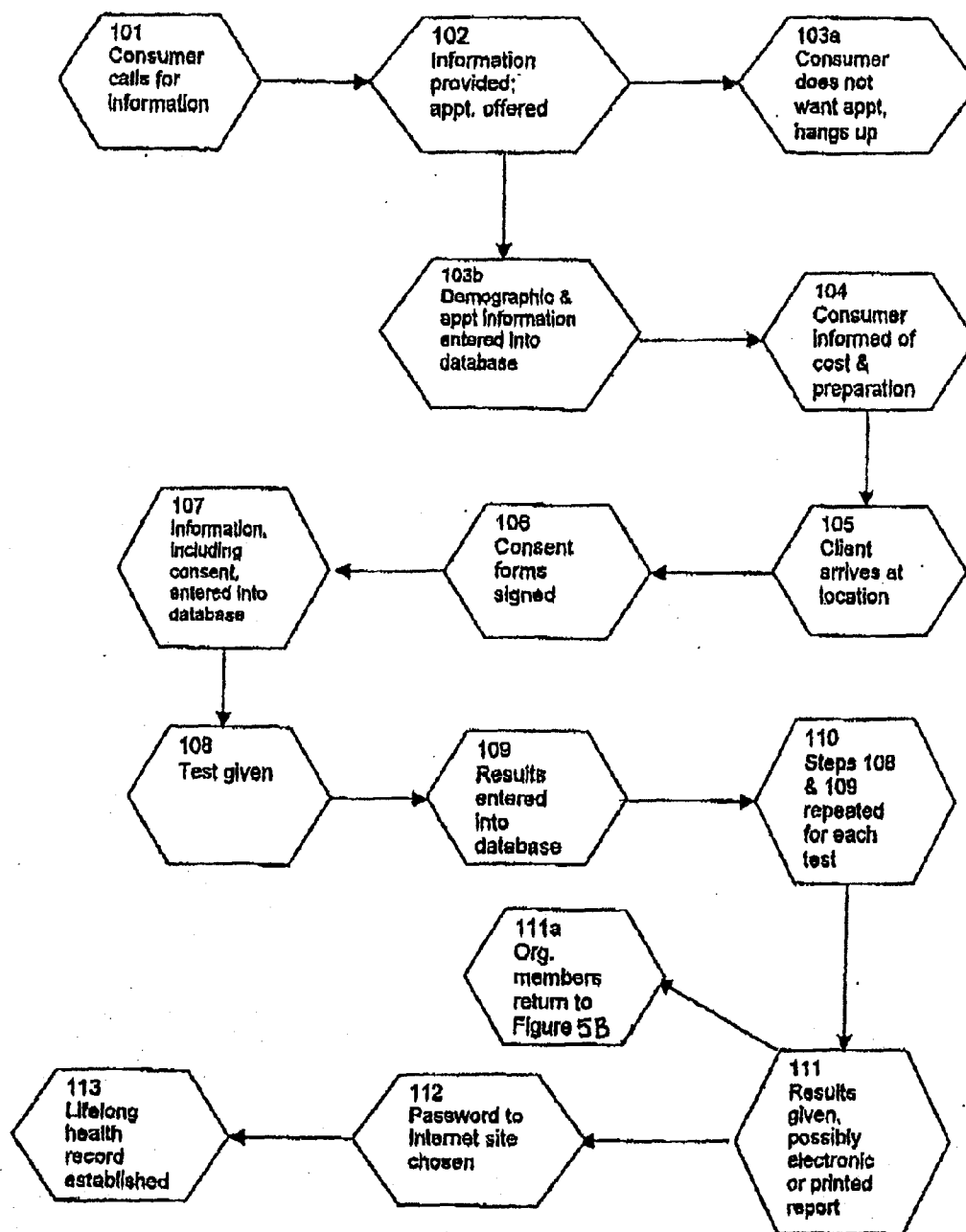


FIG. 5A

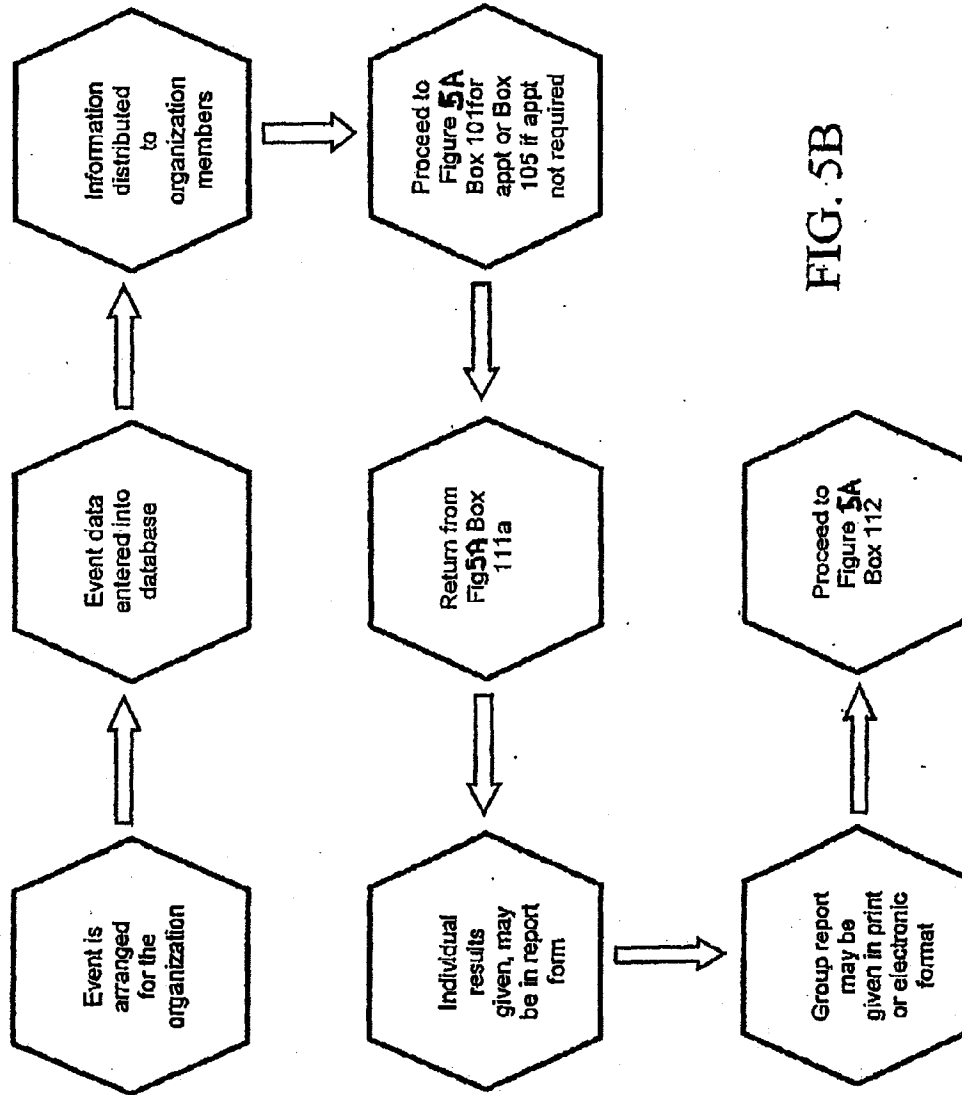


FIG. 5B

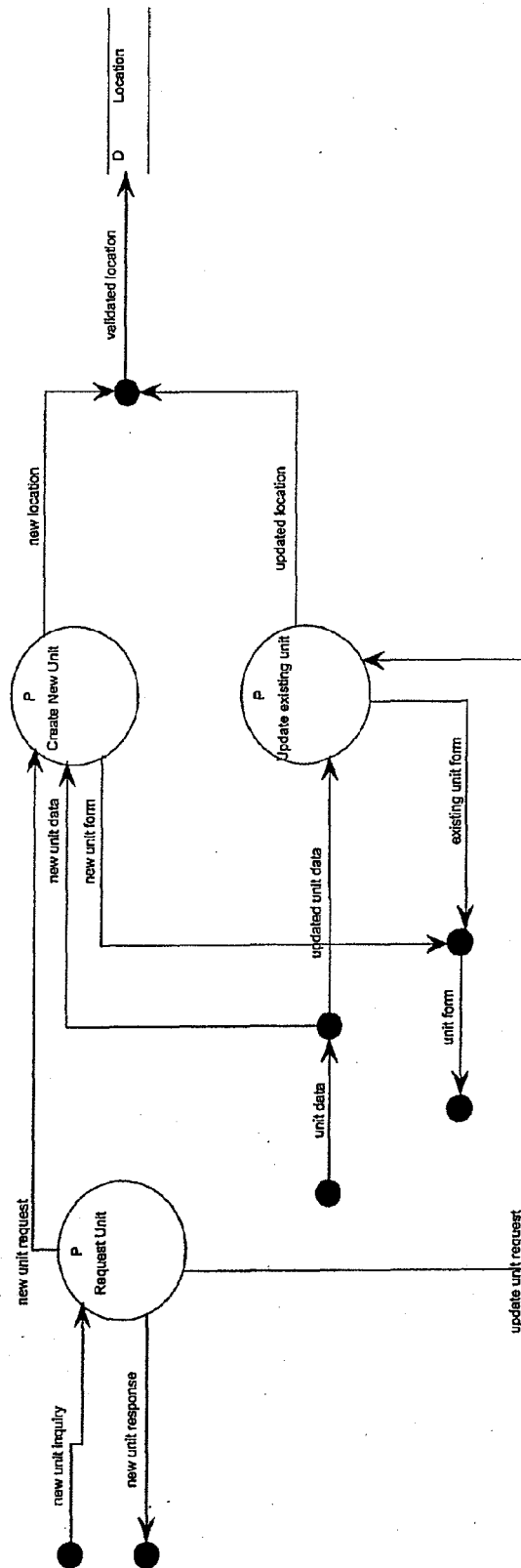


FIGURE 6A

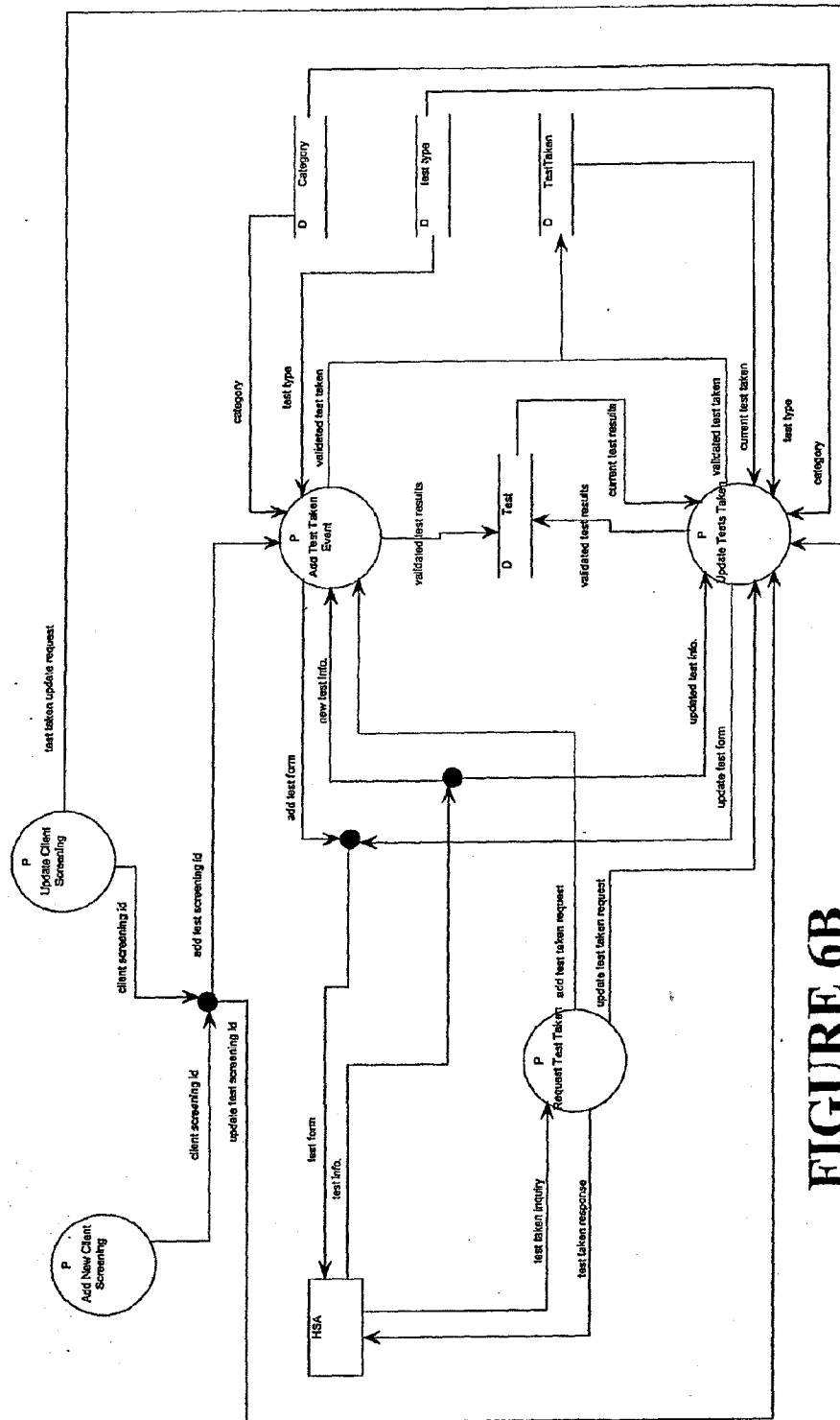


FIGURE 6B



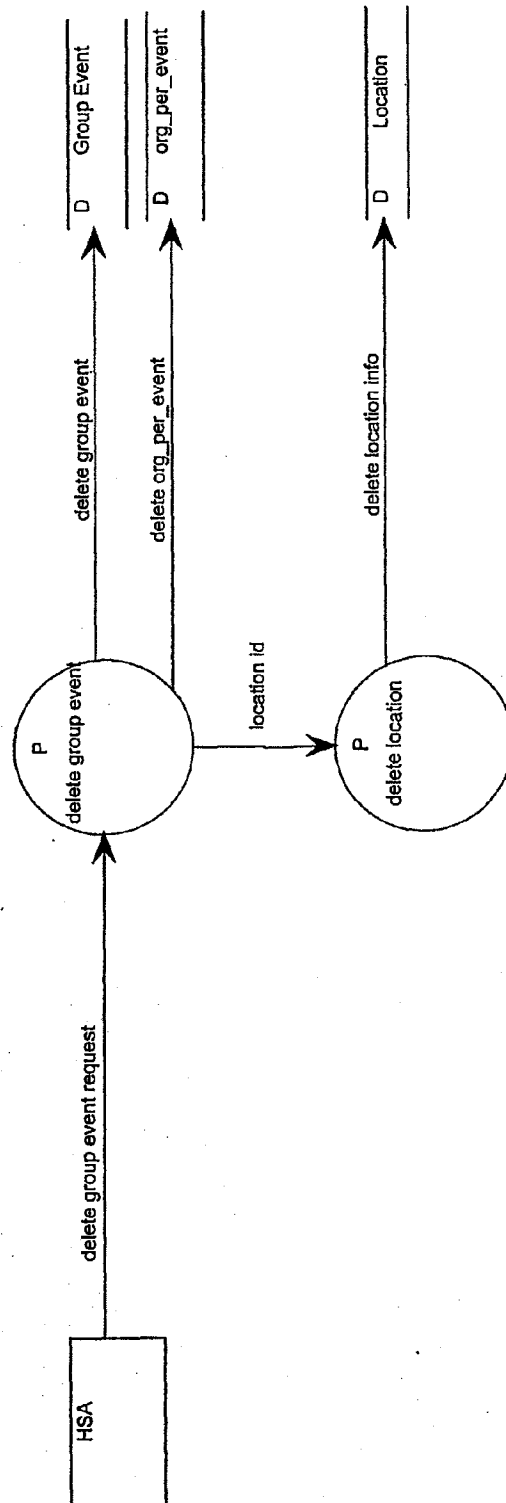


FIGURE 6C

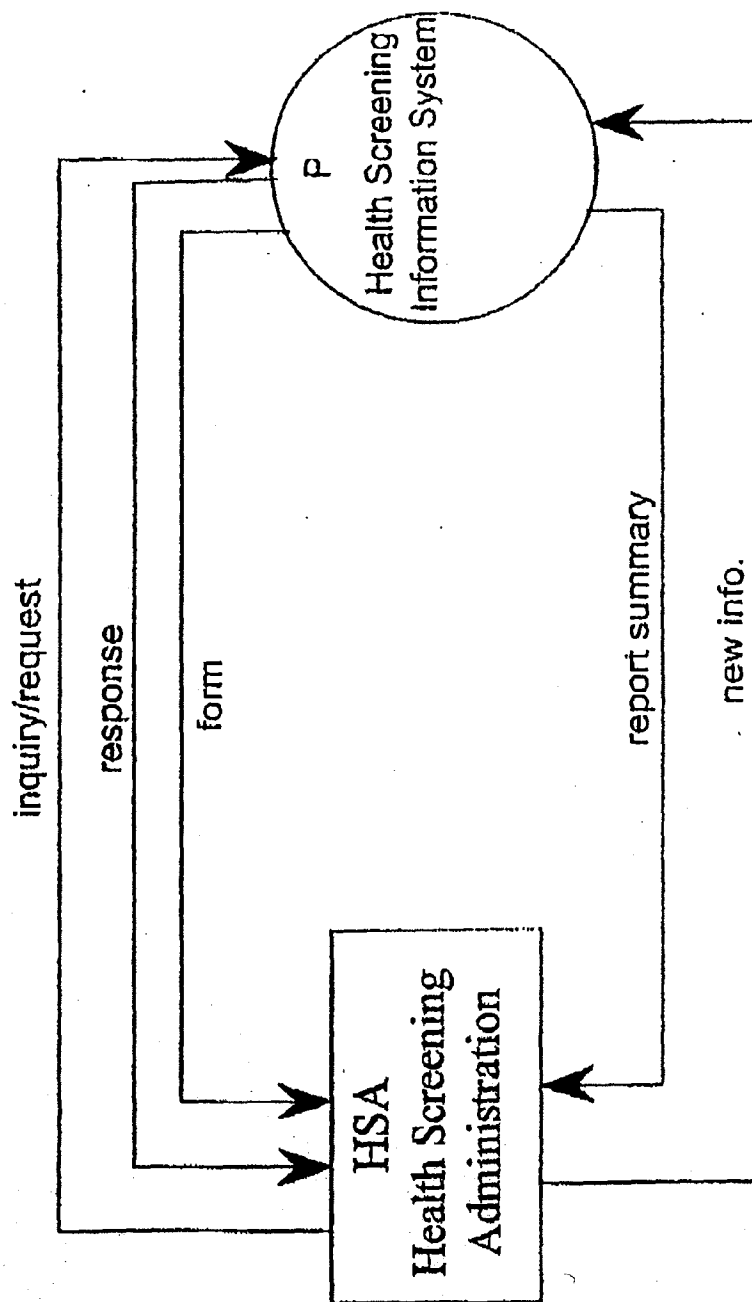


FIG. 6E

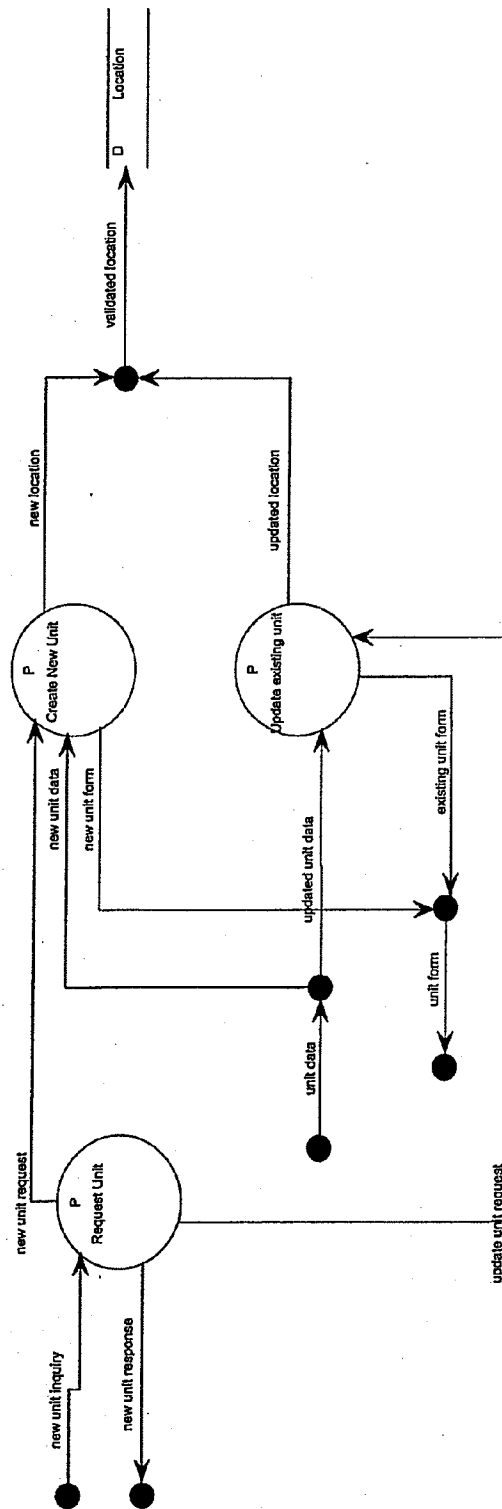


FIGURE 6D

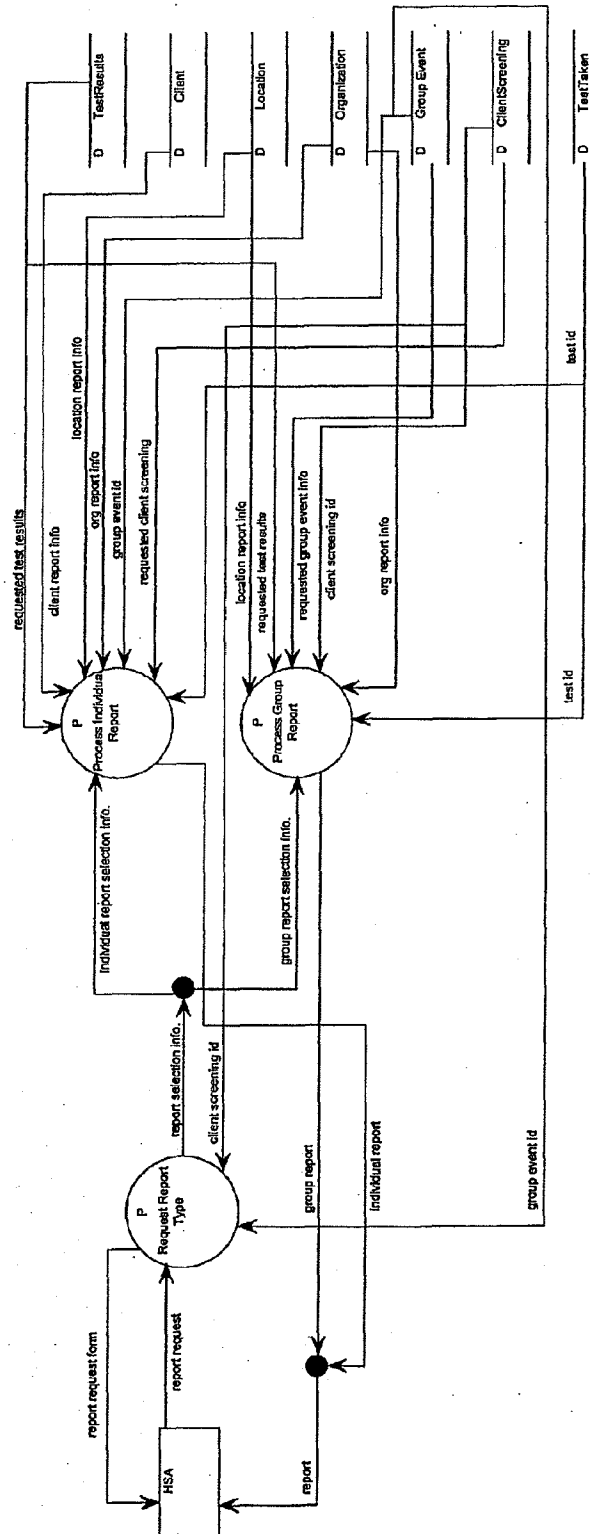
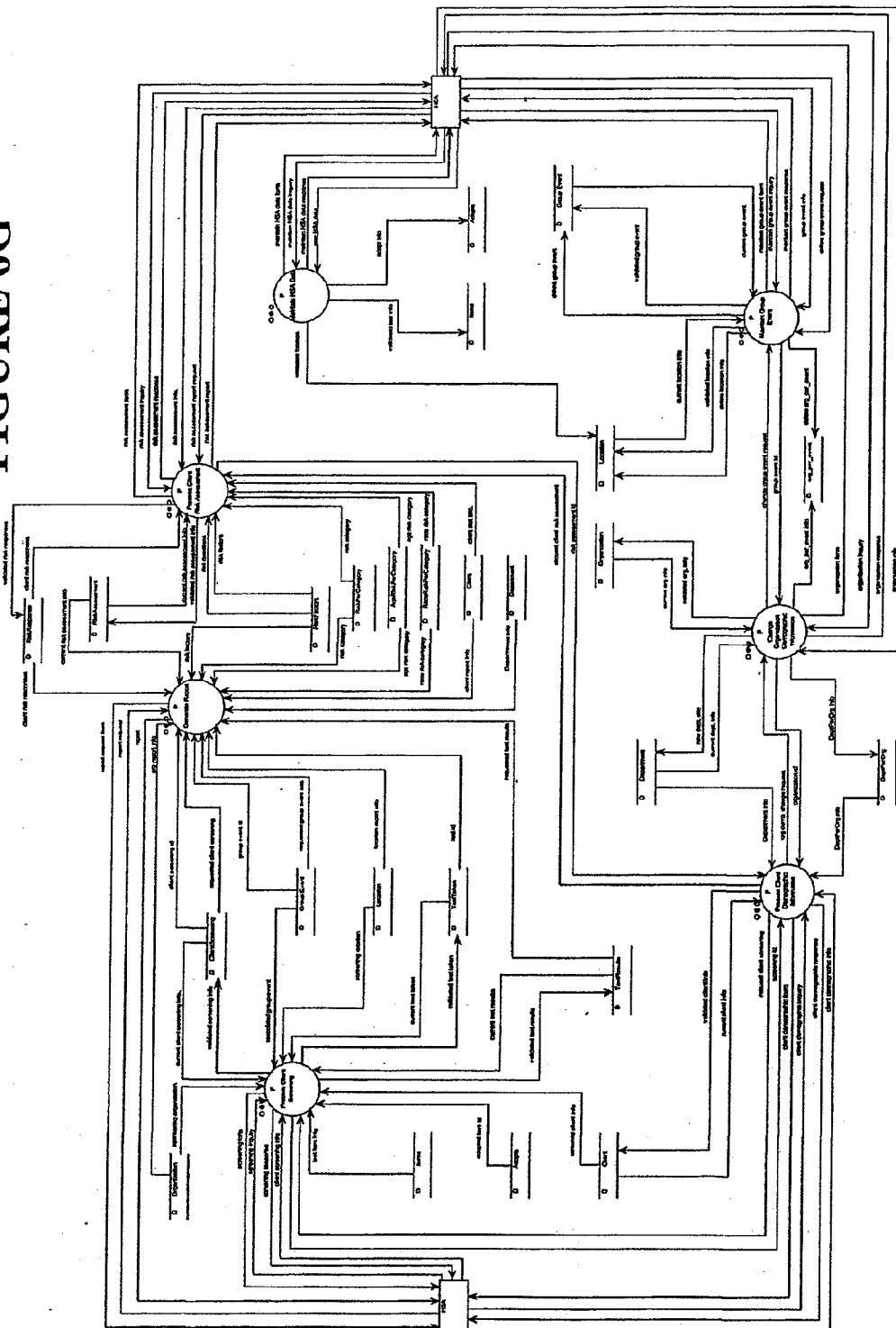


FIGURE 6F

FIGURE 6G



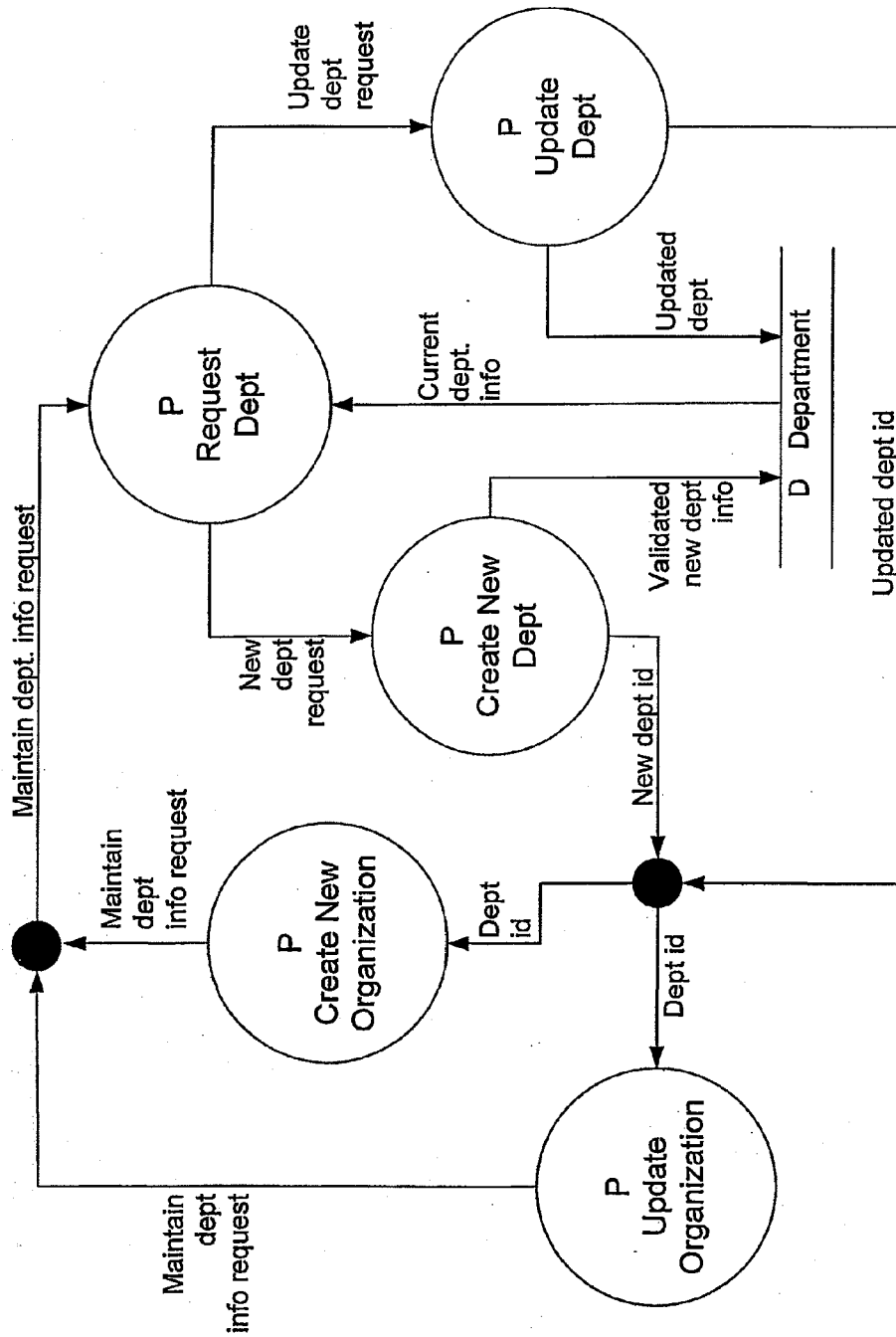


FIG. 6H

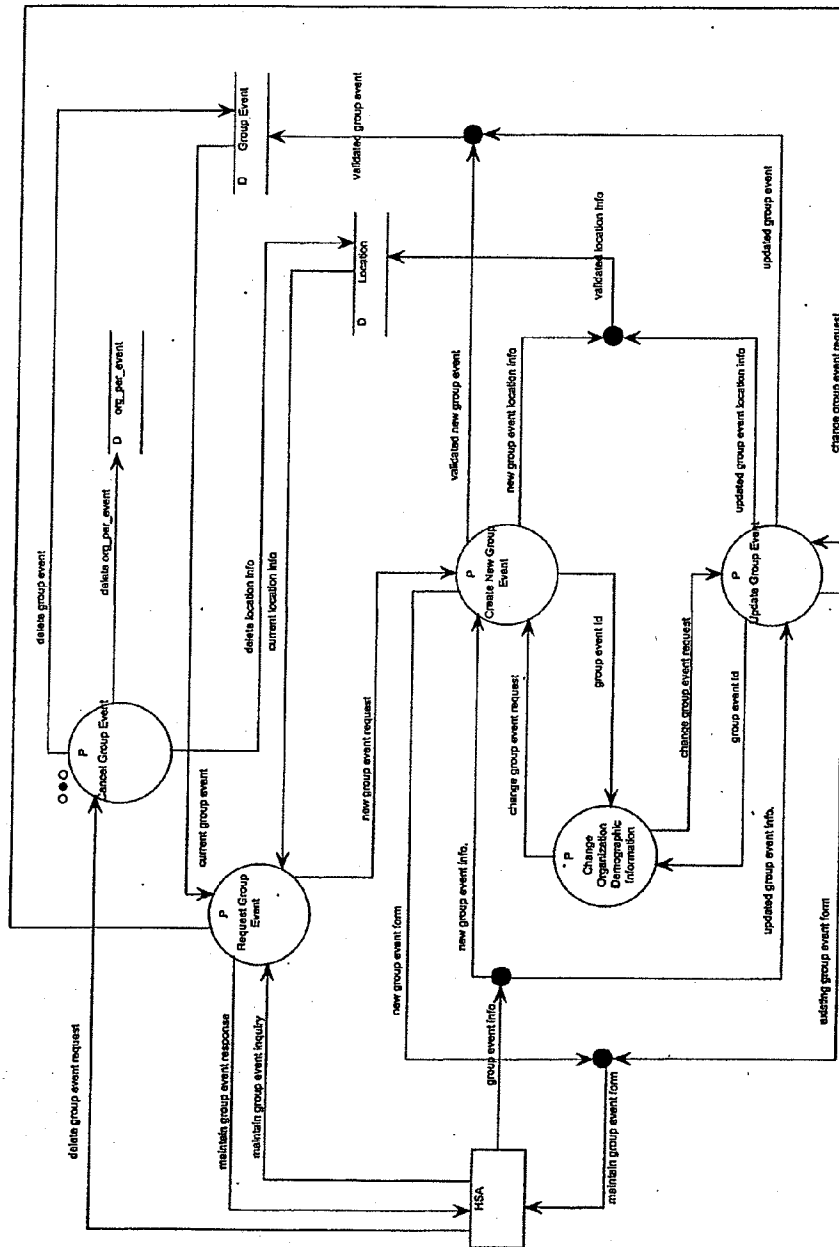


FIGURE 6I

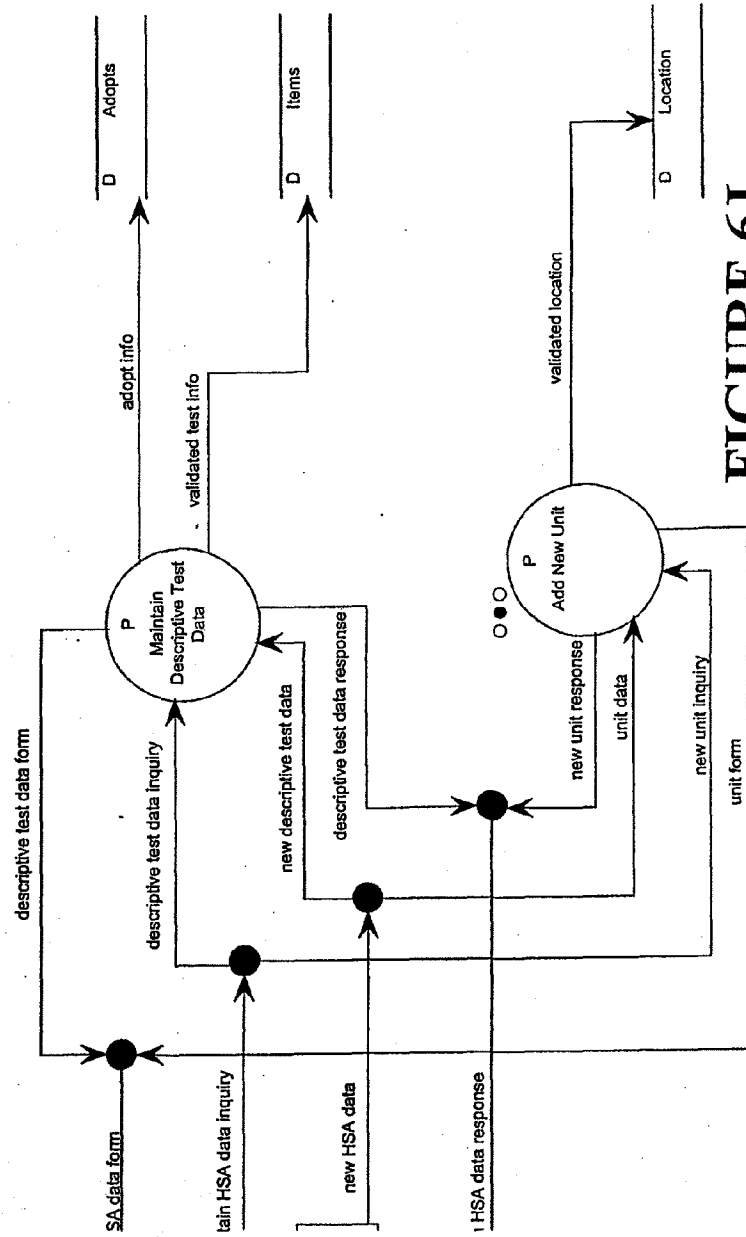
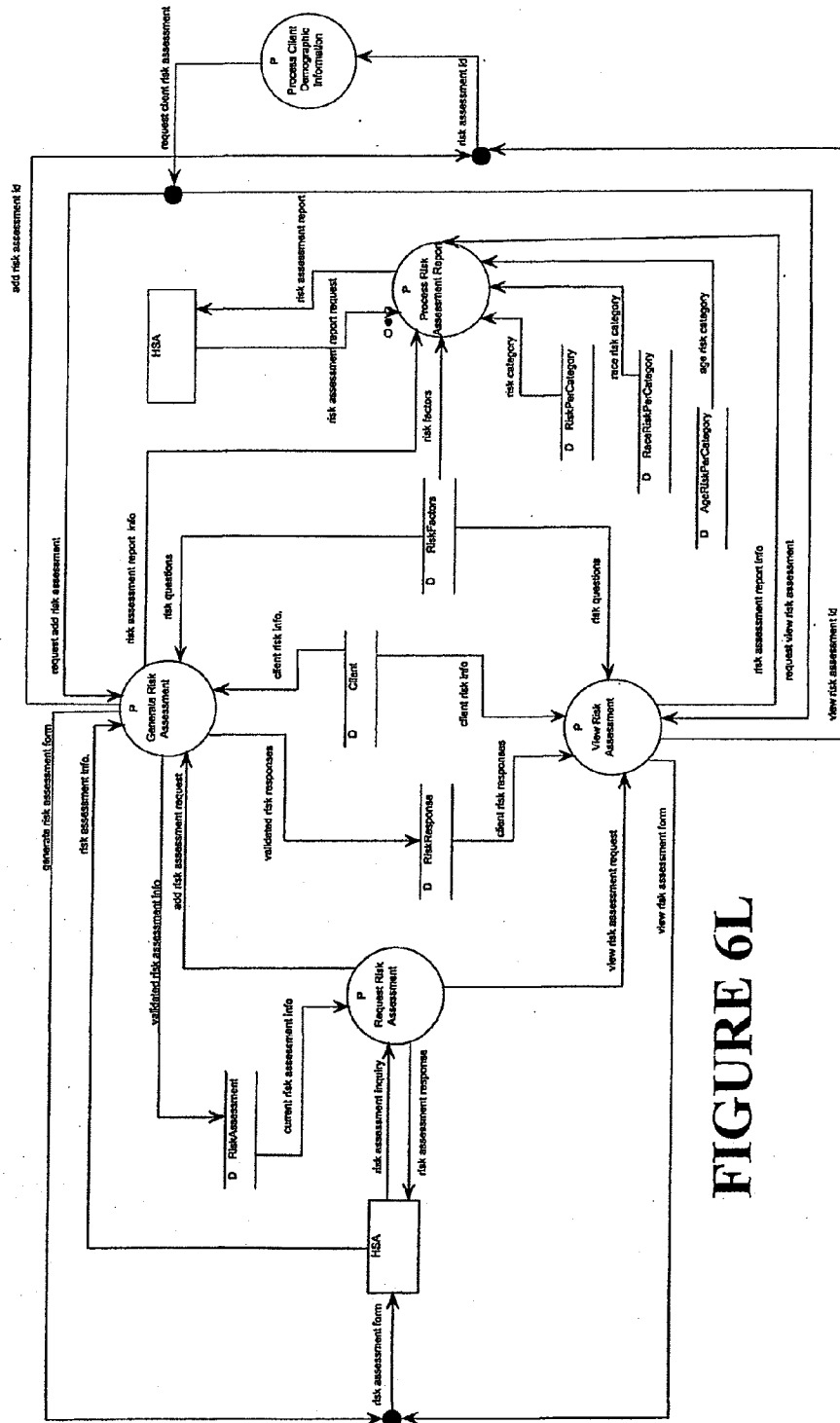


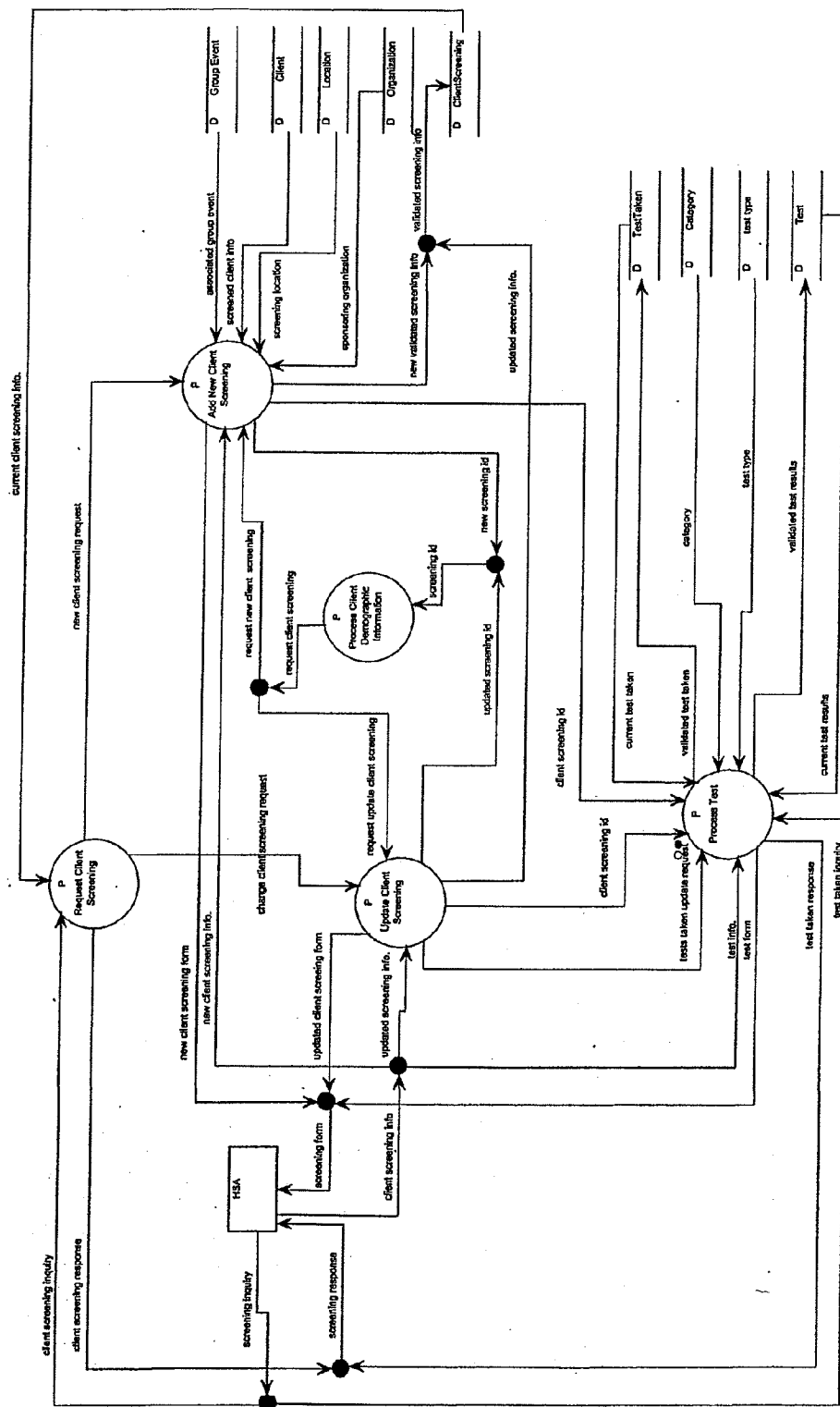
FIGURE 6J







**FIGURE 6L**



## FIGURE 6M

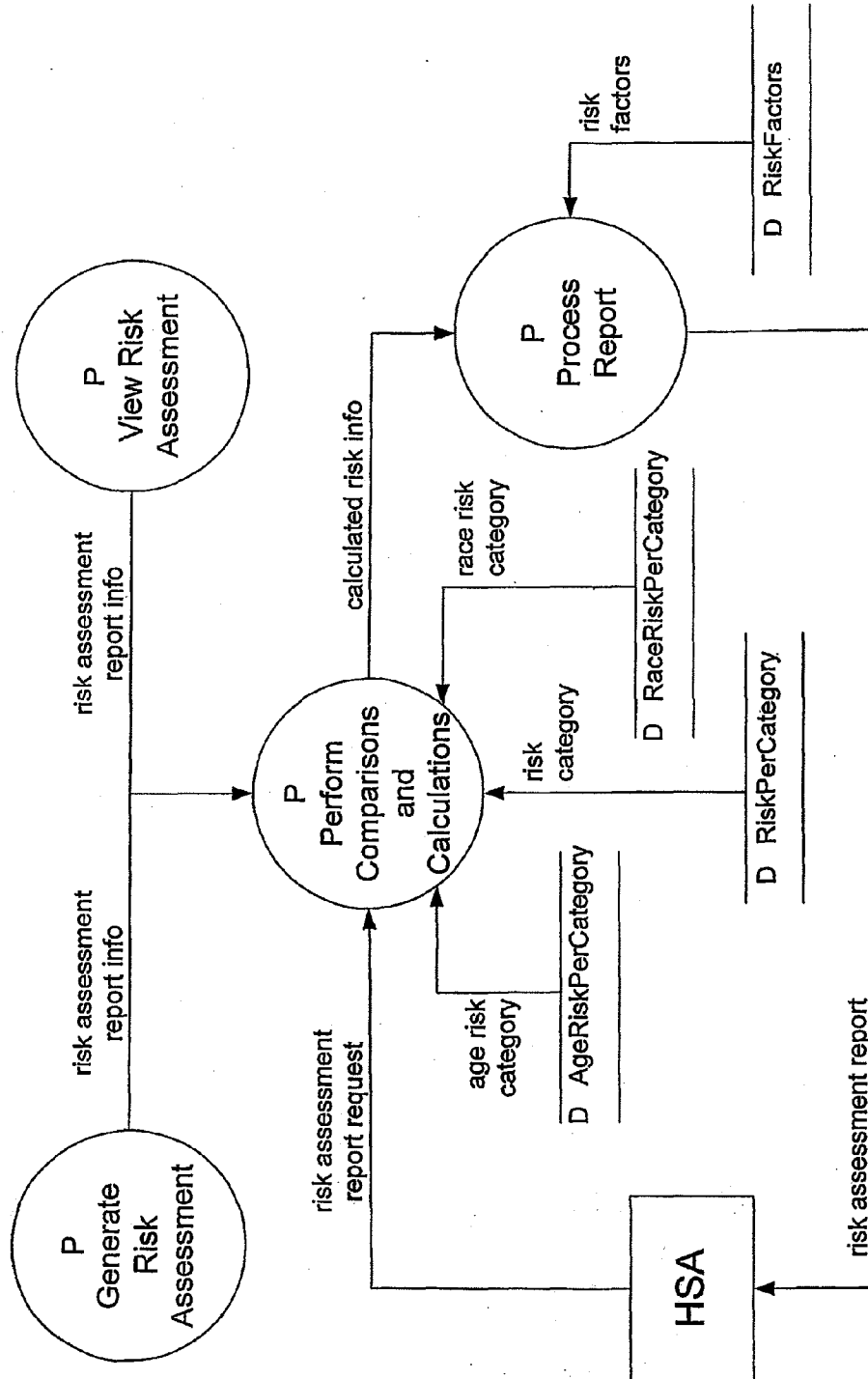


FIG. 6N

## FIGURE 7A

### John Doe's Personal Health Record

#### Information You Can Use

This record has been created especially for you by HealthScreen America to provide documentation of the results of your screening tests. The findings may help your physician identify health conditions and will help you monitor your health. By using this report along with other health information we provide, you can gain a greater understanding of your current health status and what you can do to preserve good health.

We also have established a confidential lifelong health record for you on our website, HealthScreenAmerica.com. There, you can maintain your screening results as well as add a wealth of other vitally important health information. Each time you visit HealthScreen America, your test results will be added to your Internet health record so you can track your long-term progress and compare results.

Research has shown you can dramatically increase the length and quality of life by identifying health conditions and seeking appropriate medical care early. Frequent tests to monitor these conditions, combined with educational information from our website and consultation with your personal physician, is recommended. As America's leading health-screening advocate, our mission is to help you live a longer, healthier life.

#### See Your Physician

HealthScreen America is dedicated to helping you make thoughtful choices regarding your most precious possession: your health. The information presented in your report is in no way a substitute for a careful examination by a healthcare professional. You should always discuss specific health issues with your personal physician.

If you have any results that concern you or are abnormal, we strongly encourage you to see your doctor as soon as possible. Please be aware that no tests, including those conducted at the nation's top medical facilities, offer accurate results 100% percent of the time. Also, all test have limitations and can not detect all diseases present in the body. In many cases, your physician will want to conduct further testing. HealthScreen America recommends, in the strongest possible terms, that your healthcare regimen include periodic screenings in combination with regular consultation and examinations by your physician. We also encourage you to read and learn all you can.

#### HealthScreen America's Credentials

HealthScreen America has a staff of highly skilled health care professionals supervised by a board-certified physician. Our screening tests use only the most sophisticated FDA-approved technology in conjunction with medically appropriate protocols selected by our advisory group of board-certified physicians. The protocols are based on information and recommendations from several professional medical organizations including the American Heart Association, American Diabetes Association, National Osteoporosis Association, Centers for Disease Control and Prevention, and U.S. Preventive Health.

#### Your Records Are Confidential

HealthScreen America protects the privacy of each client. We will never sell, trade, rent, disclose or otherwise make available personally identifiable information about you to any third party without first receiving your permission. The only possible exceptions are 1) when we believe, in good faith, that the law requires disclosure or 2) to protect the rights or property of HealthScreen America.

## FIGURE 7B

### SCREENING SUMMARY

#### John Doe's Test Results

The following section contains a summary of your test results. It also provides information that explains what these results mean to help you make informed decisions about your personal wellness. We have provided a separate page of your test results for your personal physician to review. We encourage you to share this information with your doctor and learn as much as you can about your body, its processes and how to stay healthy.

TEST	YOUR RESULTS	NORMAL RANGE
<b>BODY COMPOSITION</b>		
Height:	71 in	
Weight:	185 lbs	
Body Mass Index:	25.8 kg/m <sup>2</sup>	Normal: 18.5 - 24.9 kg/m <sup>2</sup>
Total Body Fat:	18 %	Women: 19% - 26% Men: 12% - 18%
<b>CARDIOVASCULAR</b>		
Blood Pressure:	125 / 80 mm Hg	<130 / <85 mm Hg
Pulse (Heart Rate):	77 bpm	60 - 100 bpm
Total Cholesterol:	196 mg/dL	0 - 200 mg/dL
HDL:	45 mg/dL	35 - 150 mg/dL
Cholesterol/HDL Ratio:	3.0	1.0 - 4.5
LDL:	126 mg/dL	0 - 130 mg/dL
Triglycerides:	126 mg/dL	0 - 199 mg/dL
Arterial Elasticity: Pulse Pressure	45 pulse pressure	30-50
Ankle Brachial Index:		
Right Ankle	111 mm Hg	
Right Brachial	142 mm Hg	
Right ABI	1.28	Greater than 0.95
Left Ankle	109 mm Hg	
Left Brachial	130 mm Hg	
Left ABI	1.17	Greater than 0.95
Carotid Artery Scan:		
Right ICA Velocity:	45 cm / sec	< 110 cm/sec
Right CCA Velocity:	61 cm / sec	< 110 cm/sec
Right ICA/CCA Ratio:	0.74	< 1.8
Right Plaque Grade:	None/Minimal	None/Minimal
Left ICA Velocity:	46 cm / sec	< 110 cm/sec
Left CCA Velocity:	60 cm / sec	< 110 cm/sec
Left ICA/CCA Ratio:	0.77	< 1.8
Left Plaque Grade:	None/Minimal	None/Minimal
Comments:		
Abdominal Aortic Aneurysm:		
Aortic Diameter:	1.8 cm	Less than 3 cm
Aortic Plaque Grade:	None/Minimal	
Comments:		

## FIGURE 7C

<b>DIABETES</b>		
Blood Glucose	93 mg/dL	Less than 126 mg/dL
<b>OSTEOPOROSIS</b>		
T-Score:	2.4 SD	greater than -1 SD compared your peak density
<b>LUNG CAPACITY</b>	3.24 FEV-1 4.10 FVC	75 %Predicted (nl >80%) 77 %Predicted (nl >80%)
<b>THYROID SCAN</b>	Normal	Negative
Comments:		
<b>METABOLIC AND BIOCHEMICAL STUDIES (Blood Work)</b>		
NOTE: Results for metabolic and biochemical studies require analysis by an FDA-approved laboratory that is not on the HealthScreen America premises. Your results will be mailed in approximately five to seven days.		
<b>CT SCAN (available March, 2000)</b>		
Heart CAC Score:		CAC score of zero.
Lung CT Result:		Negative

### UNDERSTANDING YOUR RESULTS

It is important to understand that no testing procedures, including those performed in physicians' offices and medical facilities, offer 100-percent diagnostic reliability. Our goal is to provide you with the highest-quality information to help you and your doctor make thoughtful decisions about your health. The screening results that HealthScreen America provides to you in no way substitute for a careful examination and regular medical care by a qualified healthcare professional.

In reading your test results, please keep in mind that a single test on its own offers minimal diagnostic value, but when combined with additional results it can significantly aid a physician's ability to diagnose important medical conditions. We encourage you to learn more about your test results and potential conditions by reading the following explanations as well as other information you gather. You also can ask for a consultation with our Registered Nurse Educator.

## FIGURE 7D

Within healthy limits, your body's fat serves many useful functions. It helps insulate, protect and contour the body as well as provides a store of energy. But excess body fat can increase your risk for several diseases.

One hundred million Americans are overweight, putting their health at risk. The reasons for weight gain can include an inherited predisposition, poor dietary habits, a stressful environment, lack of exercise or even serious medical conditions.

### YOUR RESULTS

Weight: 185 lbs  
 % Body Fat 18 %  
 Body Mass Index 25.8 kg/m<sup>2</sup>

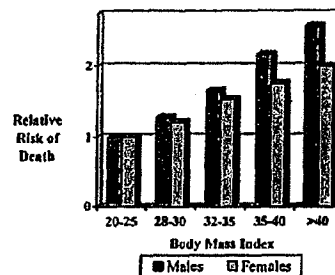
### BODY FAT NORMAL RANGES

For Women: 19% - 26%  
 For Men: 12% - 18%

### BODY MASS INDEX RISK

Normal: 18.5 - 24.9 kg/m<sup>2</sup>  
 Moderate: 25.0 - 29.9 kg/m<sup>2</sup>  
 High: 30.0 - 39.9 kg/m<sup>2</sup>  
 Very High: Over 40 kg/m<sup>2</sup>

Body Mass Index and Mortality



This graph shows that having a higher body mass index increases your relative risk of death. A relative risk of 1.0 means you are at normal risk for death. But a relative risk of 2.0 means that death is twice as likely to occur, and a relative risk of 3.0 means death is three times as likely. (Adapted from Body Mass Index and Mortality, Calle et al., NEJM 1999; 341:15. American Cancer Society study of a million adults over a 14 year period.)

### Body Metrics

The body mass index (BMI) is simply a measure of the ratio of your weight relative to your height. The portion of your body mass from fat also is reported along with the normal healthy range for body fat percentages. These measures can assist you and your physician in determining your optimal body composition.

### Associated Health Risks

The American Cancer Society conducted a 14-year study of one million adults and found that being overweight (a body mass index of 25 or higher) is associated with an increased risk of death from cardiovascular disease as well as cancer.

### Recommendation

If your test results indicate you are overweight, you should consider an effective weight loss program in consultation with your personal physician. Lifestyle modifications, including healthy eating patterns, nutritional education and regular exercise, usually form the foundation for lifelong weight management. If you received abnormal results on any of your body composition tests, we also suggest you consider the following tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Blood and Pulse Pressure, Carotid Artery Scan, Cholesterol, Diabetes, Lung Capacity and Homocysteine.

### Testing Protocol

HealthScreen America uses the Body Comp Scale™ to determine your weight and body composition analyses. This device is FDA approved and accurate to within 2.5% of underwater weight testing. These tests were performed when you stepped onto a device similar to a weight scale.



## FIGURE 7E

### CARDIOVASCULAR

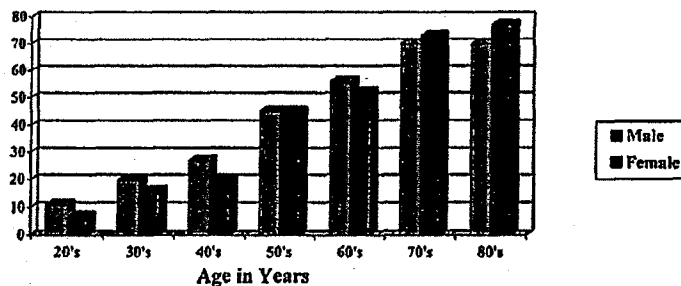
Cardiovascular disease is the leading cause of death for both men and women in the United States. The American Heart Association estimates that some form of this disease affects one in three Americans. HealthScreen America performs several screening tests to assist you and your physician in determining if you are at risk.

Early detection of risk factors aids in the timely diagnosis of disease and can prevent potentially disastrous complications. Cardiovascular risk factors include high blood pressure, elevated cholesterol, diabetes, smoking, obesity and a family history of heart disease.

HealthScreen America's cardiovascular screening tests help detect disease and prevent complications and can include:

Screening	Disease	Complication to be prevented
Blood Pressure	Hypertension	Stroke
Cholesterol	Heart Disease	Heart Attack
Arterial Brachial Index	Peripheral Vascular Disease	Amputation
Abdominal Aortic Aneurysm Scan	Aneurysm	Death

Cardiovascular Disease Incidence



The incidence of cardiovascular disease increases dramatically for both men and women as they age.

### CHOLESTEROL

The National Cholesterol Education Program recommends that all adults over 19 years of age should undergo serum cholesterol screening. An estimated 52 million American adults, could benefit from cholesterol lowering therapy. Unfortunately, many individuals have not been screened and do not know their cholesterol levels. HealthScreen America can help.

## FIGURE 7F

### CHOLESTEROL continued

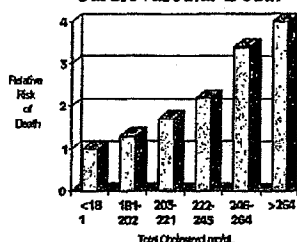
#### Your Results

Total Cholesterol (TC): 196 mg/dL  
 HDL (Good Cholesterol): 45 mg/dL  
 Cholesterol/HDL Ratio: 3.0  
 LDL (Bad Cholesterol): 126 mg/dL

#### Normal Range

Total Cholesterol (TC): 0 - 200 mg/dL  
 HDL (Good Cholesterol): 35 - 50 mg/dL  
 Cholesterol/HDL Ratio: 1.0 - 4.5  
 LDL (Bad Cholesterol): 0 - 130 mg/dL

Cholesterol Level and Risk of Cardiovascular Death



This graph shows that the relative risk of death increases with higher cholesterol levels. A relative risk of 1.0 indicates a normal risk for death. A relative risk of 2.0 means that death is twice as likely to occur, and so forth. (Adapted from Multiple Risk Factor Intervention Trial data for 361,662 men over six years. *Lancet*, 10/86.)

#### Associated Health Risks

Cholesterol is a fat-like substance (lipid) found in our cells, our food and our blood. When cholesterol levels are elevated, the cholesterol can be deposited and accumulate within the walls of arterial blood vessels. This gradually leads to vascular injury, plaque formation, inflammation and the blockage of normal blood flow. The "bad" cholesterol or LDL promotes this process, while the "good" cholesterol, HDL, can remove lipid buildup from your blood vessels. Knowing your entire lipid profile is essential to understanding your risk.

#### Recommendations

As the accompanying graph shows, a desirable level of total cholesterol is generally less than 200 mg/dL. The good cholesterol, HDL, should be greater than 35 mg/dL; the higher the better. The total cholesterol/HDL ratio is a useful means of quickly determining cardiovascular risk. A desirable ratio is 4.5 or lower.

It is important to know that if you have other cardiovascular risk factors, you should try to maintain your LDL at less than 130 mg/dL. Those with known coronary heart disease will want their LDL less than 100 mg/dL or even lower, if recommended by their physicians. Your situation is unique, and you should review and discuss your results with your physician. In general, guidelines for controlling your cholesterol include:

1. Know your cholesterol profile and track it regularly;
2. Maintain a healthy body weight;
3. Practice good nutrition, such as a diet high in fiber, low in cholesterol and low in saturated fat;
4. Consider an exercise program after consulting your physician.

If any of your cholesterol tests are abnormal, we also suggest you consider the following HealthScreen America screening tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Blood and Pulse Pressure, Body Composition, Carotid Artery Scan and Homocysteine.

#### Testing Protocol

HealthScreen America utilizes the Cholestech LDX system to obtain your lipid profile. A simple finger prick blood sample is all that is required. The Cholestech system is FDA-approved and proven to achieve accuracy that was previously attainable only from clinical laboratories.

## FIGURE 7G

### TRIGLYCERIDES

Triglycerides are a form of fat that is found in the body and in the food we eat.

**Your Results**  
126 mg/dL

Normal Ranges	
Desirable	0 - 199 mg/dL
Moderate:	200 - 399 mg/dL
High:	400 - 999 mg/dL
Very high:	More than 1000 mg/dL

#### Associated Health Risks

Elevated triglycerides are often closely associated with obesity and diabetes. Other causes of elevated triglyceride levels include inherited conditions that can lead to premature cardiovascular death as well as disorders of the thyroid, kidneys or liver.

#### Recommendations

If your test results fall outside the normal range, we encourage you to notify your physician. Maintaining a healthy body weight, reducing saturated fat and cholesterol in your diet, and regular exercise are often recommended to those with high triglyceride levels.

If your triglyceride levels are abnormal, we suggest you also consider taking the following tests: Cholesterol, Metabolic Studies, Abdominal Aortic Aneurysm, Ankle Brachial, Blood and Pulse Pressure, Body Composition, Carotid Artery Scan and Homocysteine.

#### Testing Protocol

We evaluated your triglyceride level from a sample of your blood, using sophisticated, FDA-approved measurement technology.

### ARTERIAL STUDIES

Your arteries form a tree that distributes blood, with vital oxygen and nutrients, throughout the body. Abnormalities of this system can be the source of complications such as stroke, non-healing ulcers, numb or cold extremities, painful leg cramps and even amputation or sudden death.

HealthScreen America provides several screening procedures to determine the health of your arterial system. These include:

1. Blood Pressure
2. Pulse Pressure
3. Ankle Brachial Index
4. Carotid Artery Scan
5. Abdominal Aortic Aneurysm Screen

### BLOOD PRESSURE

High blood pressure (hypertension) is one of the most important modifiable risk factors for cardiovascular disease. It affects 43 million American men and women. Sadly, about a third of these individuals are unaware they have the problem. Even when high blood pressure is correctly diagnosed, it is often under treated and poorly controlled. The Health Statistics National Health and Nutrition Survey III found that more than 70 percent of those with hypertension did not have the condition under adequate control.

## FIGURE 7H

### BLOOD PRESSURE

Your results are expressed as a ratio, for example 120/80 mm Hg. The first number is the systolic reading and indicates the pressure in the brachial artery (upper arm) is 120 mm Hg during the pumping phase of the heart. The second number is the diastolic and it means that when the heart is between beats, the blood pressure is 80 mm Hg. HealthScreen America measured your blood pressure by using a pressure cuff that was placed around your upper arm and connected to an advanced, FDA-approved cardiovascular-evaluation device. The blood pressure criteria of the Joint National Committee of Detection, Evaluation and Treatment of High Blood Pressure (JNC-VI) presented below help you interpret your results.

**Your Results**  
BP Systolic (top #): 125 mmHg  
BP Diastolic (bottom #): 80 mmHg

Normal Ranges	Systolic (top#)	Diastolic (bottom#)	
Normal	less than 130	less than 85	
High Normal	130-139	85-89	
<b>Hypertension</b>			
Moderate	(stage 1)	140-159	90-99
High	(stage 2)	160-179	100-109
Very High	(stage 3)	180-209	110-119
Critical	(stage 4)	more than 210	more than 120

#### Associated Health Risks

Hypertension often is a silent killer, causing no symptoms. If untreated, it can lead to complications such as heart attack, stroke, congestive heart failure, kidney failure and peripheral vascular disease.

#### Recommendation

Because each individual's blood pressure can vary, several readings should be taken for an accurate evaluation. If your blood pressure falls outside the normal range, we suggest you consult a physician to determine whether follow-up action is needed. Your physician may prescribe medications or a special diet to help control your blood pressure.

If your blood pressure is high, we also recommend considering the following tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Body Composition, Carotid Artery, Cholesterol and Diabetes.

### PULSE PRESSURE

Arteriosclerosis is a medical term indicating a literal "hardening" of the arteries. This process occurs as a result of age as well as several disease processes. Fortunately, modern technology has given us a non-invasive way to evaluate the stiffness of your arterial system, providing you with a warning of possible problems ahead.

**Your Results** 45      **Normal Range of Pulse Pressure**

30 to 50

#### Associated Health Risks

Decreased arterial elasticity or decreases in the flexibility of an artery may indicate hardening or arteriosclerosis from cardiovascular disease. One of the best indicators of this process is the pulse pressure. Elevations of pulse pressure have been shown to predict cardiovascular disease and death.

#### Recommendations

If your test results indicate an elevation of your pulse pressure, you should review them with your physician.

If your results are abnormal, we also recommend taking the following HealthScreen America tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Body Composition, Carotid Artery Scan, Cholesterol and Homocysteine.

## FIGURE 7I

### PULSE PRESSURE continued

#### Testing Protocol

HealthScreen America uses a FDA approved device for this test. The simple, painless test uses a pressure cuff placed on your upper arm. Your pulse pressure is determined by subtracting the diastolic measurement (the lower value) from the systolic reading (the upper value). As arterial health and elasticity decrease, the pulse pressure will increase.

### ANKLE BRACHIAL INDEX

The Ankle Brachial Index (ABI), test is a useful screening test for peripheral vascular disease, which results in a lack of proper circulation.

#### Your Results

	Ankle	Brachial	Ratio
Right	111mm Hg	142mm Hg	1.28
Left	109mm Hg	130mm Hg	1.17

Ranges	ABI
Normal	> 0.95
Mild obstruction:	0.71 - 0.95
Moderate obstruction:	0.31 - 0.70
Severe obstruction:	0.00 - 0.30

#### Associated Health Risks

This test is useful in determining your risk for peripheral vascular disease, a narrowing or blockage of the arteries that carry blood to your arms and legs. This condition can lead to cool, numb or painful hands and feet, non-healing ulcers or even amputation.

#### Recommendations

If your Arterial Brachial Index is lower than 0.96 it may be related to obstruction in your arteries and peripheral vascular disease. You should bring the results to the attention of your physician, who can determine your need for further evaluation and treatment.

We suggest you also consider taking the following tests: Abdominal Aortic Aneurysm, Arterial Elasticity, Body Composition, Carotid Artery Scan, Cholesterol and Homocysteine.

#### Testing Protocol

The FDA-approved Unetixs ABI device was used to evaluate your ABI. Pressure cuffs were placed on your arms and legs to measure blood flow. This system applies computerized Doppler technology to determine test results rapidly.

### CAROTID ARTERY SCAN

This screening test evaluates the condition of your carotid arteries, the main arteries supplying blood to the brain and face.

#### Your Results

	Right	Left
ICA velocity:	45cm /sec	46cm /sec
CCA velocity:	61cm /sec	60cm /sec
ICA/CCA ratio:	0.74	0.77
Plaque grade:	None/Minimal Critical	None/Minimal

Velocity	Degree of Blockage:	Risk:
<110cm/sec	0 - 40%	Low- Mod
>120cm/sec	41 - 59%	High
>130cm/sec	60% to 79%	Very High
	>250cm/sec	Greater than 80%

#### Associated Health Risks

When arteriosclerosis and cholesterol plaques affect the carotid arteries, a build-up or release of debris in the artery can suddenly block blood flow and cause a disabling or fatal stroke in the brain.

## FIGURE 7J

### CAROTID ARTERY SCAN continued

#### Recommendations

It is important to note this test is not designed to produce diagnostic results, but to detect possible problems. The carotid scan determines the how fast the blood is flowing within your common carotid artery (CCA) and your internal carotid artery (ICA). These arteries supply the majority of blood to the brain and face. By detecting abnormal velocities the carotid scan can determine if there is evidence of blockage present within the artery.

If your results are abnormal, you should consult with your physician for further evaluation immediately. The ICA to CCA ratio is also reported and should be less than 1.8. If abnormal, your physician should seek further testing. The degree of blockage present in the carotid arteries will help guide your physician in your treatment and whether there is any need for surgical intervention. Be sure to review your results with your physician.

As part of your overall assessment for heart attack and stroke, you should also consider taking the following tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Blood and Pulse Pressure, Body Composition, Cholesterol and Homocysteine.

#### Testing Protocol

The (Siemens and/or GE) ultrasound scanner wand is applied to the side of the neck with gentle pressure. This FDA-approved device uses high-frequency sound waves that bounce off the carotid artery. It creates actual images of the arteries and can "look inside" to determine the presence of blockage.

### ABDOMINAL AORTIC ANEURYSM SCAN

The aorta is the largest blood vessel in the body. It is the main channel for blood leaving the heart and circulating to the rest of the body. Throughout your lifetime, it is subjected to the blood flow and pressure of each and every heartbeat.

#### Your Results

Aortic Diameter: 1.8cm

#### Normal Range

Less than 3 cm	Within normal limits
3 to 5 cm	Aneurysm requiring evaluation
More than 5 cm	High risk for rupture, seek medical attention immediately

#### Associated Health Risks

Over time, the walls of the aorta can weaken and expand. This process is known as aortic aneurysm formation. There are an estimated 1.5 million adults with this condition but only a fraction will be aware of the risk they face. Ruptures of aortic aneurysms are responsible for the sudden deaths of approximately 15,000 Americans each year.

#### Recommendations

If your Abdominal Aortic Scan shows an aortic diameter of 3 cm or more, you should review these results with your personal physician. Often it is necessary to follow an aortic aneurysm closely to ensure it is not enlarging over time and at risk for sudden rupture.

We also suggest you consider the following HealthScreen America tests: Ankle Brachial Index, Body Composition, Carotid Artery Scan, Cholesterol and Homocysteine.

#### Testing Protocol

A FDA-approved (Siemens and/or GE) scanner uses ultrasound waves to form images of the aorta, determining the aortic diameter. A small ultrasound wand was gently passed over the abdominal area.

## FIGURE 7K

### DIABETES

There are two types of diabetes: Type I is caused by the complete lack of insulin production, while Type II is caused by insufficient or ineffective insulin. Type I diabetes often occurs in childhood while Type II diabetes, also known as "adult onset" diabetes, is closely linked to obesity. Being overweight can lead to "insulin resistance". Insulin is a hormone produced by the pancreas that is important in carbohydrate, protein and fat metabolism. Often those with early stage diabetes have no obvious symptoms, but warning signs are listed below.

#### Warning Signs of Diabetes

1. Frequent urination
2. Excessive thirst
3. Dry mouth
4. Blurred vision
5. Poor wound healing
6. Recurrent infections
7. Numbness or tingling
8. Erectile dysfunction (impotence)

#### Your Results

Glucose level: 93mg/dL

#### Normal Range

Normal is less than 126 mg/dL

Consult your physician if greater than 126mg/dL

#### Associated Health Risks

Diabetes is a major cause of blindness, kidney failure, amputation, heart attack and stroke. It affects more than 16 million Americans. Yet millions of individuals have never been screened, diagnosed or received needed therapy. Although there is currently no cure for the disease, it can be controlled with proper treatment. Control of diabetes can reduce the frequency and severity of associated retinal, kidney and nerve damage by 50 - 70%.

The Centers for Disease Control and Prevention (CDC) recommends that all those age 25 and older receive screening for diabetes. It estimates the average delay in the diagnosis of diabetes is 9 to 12 years from the onset of disease. Early detection can prevent years of damage to vital organs and permanent injury to your health.

#### Recommendations

If your FDA-approved fasting blood glucose is higher than 126 mg/dL, we suggest you consult your physician as soon as possible. Only a doctor can make a definitive diagnosis and determine the proper course of treatment, if needed.

If your results are abnormal, we also suggest you consider taking the Body Composition Test and Cardiovascular screening at HealthScreen America, including Blood Pressure, Cholesterol, Homocysteine, Carotid Artery Scan and Ankle Brachial Index.

#### Testing Protocol

We perform a fasting plasma glucose test using a small sample of blood obtained from an easy finger-prick.

## FIGURE 7L

### OSTEOPOROSIS

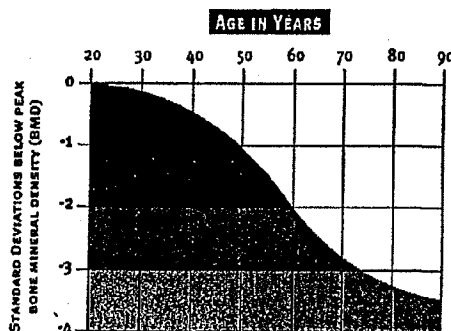
Americans are living longer than ever before, and as our population ages, osteoporosis is emerging as a major health issue. Peak bone density is reached in early adulthood (usually by age thirty), then over time the bones of your skeleton become progressively more fragile. This loss of bone density leaves one especially susceptible to fractures. Unfortunately, osteoporosis is often discovered late in the disease process. Early screening is critical to the recognition, prevention and effective treatment of osteoporosis. While the disease can occur in men, women are at higher risk and should begin screening in their 20s.

The T-Score shown here compares your bone density to that of young, healthy adults. It is usually a negative value and compares your bones to when you were young and your bones were at their strongest. The lower the T-Score the lower your bone density and more fragile your bones. Your physician will take into account many factors (such as your history, age and other risk factors) to diagnose and recommend treatment for osteoporosis.

#### Your Results

2.4 SD T-Score

Normal Range	
Greater than -1.0	SD
Osteoporosis results in:	
1.	Tooth loss
2.	Fractures of the vertebrae
3.	Back deformity
4.	Loss of mobility
5.	Chronic pain
6.	Depression and low self esteem
7.	Loss of independence
8.	Hip fractures and death



#### Health Risks

Osteoporosis is a silent epidemic affecting 28 million American women. Half of women over the age of fifty are destined to develop osteoporosis in their lifetime. Few of these women understand that the risk of death from osteoporosis is as great as the risk of death they face from breast cancer. Osteoporosis can lead to hip fracture and life-threatening complications.

#### Recommendations

If your results are outside the normal range, we strongly suggest that you bring this to the attention of your physician. A T-Score between -1.0 and -2.5, indicates your bone density is low, this is known as osteopenia. Low bone density is of concern since the bones tend to weaken over time. Thus osteopenia can be the first evidence of your risk for osteoporosis. A T-Score lower than -2.5 is regarded as osteoporosis by the World Health Organization.

You should also be aware of the risk factors for osteoporosis:

1. Caucasian, Hispanic, or Asian decent
2. Slender or small body build
3. Early menopause or postmenopausal state
4. Inadequate calcium in diet



## FIGURE 7M

### **OSTEOPOROSIS** continued

5. Lack of regular weight bearing exercise
6. High intake of caffeine or alcohol
7. Smoking
8. A family history of osteoporosis
9. Diseases such as asthma and rheumatoid arthritis

To reduce your risk, you should consider:

1. A diet or supplements with 1,200 to 1,500mg of daily calcium
2. Vitamin D 400 to 800 IU daily

#### **Testing Protocol**

This screening test is performed by placing your heel into the Lunar ultrasonometer, a FDA-approved device, which uses ultrasound technology to evaluate the density of your bones.

## FIGURE 7N

### LUNG CAPACITY

This test evaluates the condition of your lungs and their ability to expand and release air normally. It is beneficial in detecting airflow abnormalities from a variety of causes. The FVC (forced vital capacity) score tells how much air your lungs can hold. The FEV-1 (forced expiratory volume) score tells how much air you can blow out of your lungs within one second.

The number provided in the Percent Predicted column compares your lung capacity to the expected normal range. Your FVC and FEV-1 scores should be 80 percent or more of that predicted.

Your Results	Percent Predicted
3.24 FEV-1	75 %
4.10 FVC	77 %

#### Associated Health Risks

The Lung Capacity screening test can help detect lung diseases such as emphysema or chronic obstructive pulmonary disease that is often associated with smoking. It also can provide evidence of asthma or reactive airway disease. Asthma often goes undetected despite being the fifth leading cause of death in the United States.

#### Recommendation

If your Lung Capacity results are not in the normal range, we encourage you to see your doctor. Two of the best things you can do to maintain good lung health are to exercise regularly and avoid smoking.

#### Testing Protocol

The test is performed by exhaling into an FDA-approved Simplicity NPB-500 spirometer.

## FIGURE 70

### THYROID SCAN

This screening test detects abnormalities in the thyroid such as cysts, tumors, goiter (an enlargement of the thyroid gland) and nodules. The test often finds "non-palpable" nodules, which cannot be felt in a physical exam and can only be detected through medical imaging. Thyroid nodules are common, occurring in about one-third of all people, according to the American Cancer Society. The vast majority of these growths are not cancerous and pose no risk to your health.

Your Results      Normal

Normal
Abnormal

#### Comments

#### Associated Health Risks

When abnormalities are found in the thyroid, there is a possibility of a risk of thyroid cancer, and hyperthyroidism (too much thyroid hormone) or hypothyroidism (too little thyroid hormone).

Individuals at greatest risk for thyroid cancer are those with a history of exposure to radiation or a family history of thyroid cancer. Solitary thyroid nodules greater than 1.0 cm in size and those with suspicious features on a thyroid ultrasound or a thyroid nuclear scan are of the greatest concern and may require a biopsy or excision.

#### Recommendations

If thyroid abnormalities are detected, you should consult your physician for further evaluation. Multiple small nodules can develop when a thyroid goiter is present because of an underlying thyroid hormone imbalance. A metabolic screening of thyroid hormone levels is usually performed. Your personal physician will help you decide which tests are better in your situation.

As part of your overall assessment for the thyroid gland, you should also consider taking a simple blood test at HealthScreen America to determine your thyroid profile. The blood test measures the thyroxine level (T4) from the thyroid gland and a thyroid stimulating hormone level (TSH) from the pituitary gland.

#### Testing Protocol

An ultrasound scanner wand is applied to the neck with gentle pressure. This FDA-approved ultrasound device (either Siemens or General Electric) uses high-frequency sound waves that bounce off the thyroid. It creates actual images of the thyroid gland and can "look inside" to search for abnormalities.

## FIGURE 7P

### METABOLIC AND BIOCHEMICAL STUDIES

Several of the tests offered by HealthScreen America are sophisticated blood studies that require processing by an outside laboratory. These include:

- Tumor-marker tests such as CEA, CA-125 and PSA help identify cancer at an early stage
- Hormone studies such as the TSH, T4, FSH, testosterone and estrogen levels, hormone deficiencies or imbalances
- Hematologic studies that can uncover anemia or other problems involving your red cells, white cells and platelets
- Biochemical studies evaluate the health of vital organs such as the kidneys, liver, gallbladder and pancreas; also, electrolyte and chemical abnormalities can point to underlying disease
- Screening factors such as homocysteine levels are known to be associated with an increased risk of disease

These complex metabolic analyses do not lend themselves to simple discussion and explanation. Every test HealthScreen America performs is reported along with an expected normal range. The highest standards are used in these laboratory analyses. Nevertheless, no tests can always be 100-percent reliable.

**Your Results** Results require analysis of your blood sample by a national laboratory. Results will be mailed to you in five to seven days.

#### Normal Ranges

CA 125: 0 - 35 IU/mL

CEA: Smokers: 0 - 5.0 ng/mL

Non-Smokers: 0 - 3.0 ng/mL

PSA: 0 - 4 ng/mL

Blood Count:

WBC: 4.0 - 10.5  $10^3$ /uL

RBC: 4.10 - 5.60  $10^6$ /uL

Hgb: 12.5 - 17.0 g/dL

Hct: 36.0 - 50.0%

MCV: 80 - 98 fL

MCH: 27.0 - 34.0 pg

MCHC: 32 - 36 g/dL

Neutrophils: 40 - 74%

Lymphocytes: 14 - 46%

Monocytes: 4 - 13%

Eosinophils: 0 - 7%

Basophils: 0 - 3%

Abslt Cnt: Neutrophil: 1.8 - 7.8  $10^3$ /uL

Abslt Cnt: Lymphocyte: 1.0 - 4.8  $10^3$ /uL

Abslt Cnt: Monocyte: 0 - 0.8  $10^3$ /uL

Abslt Cnt: Eosinophil: 0 - 0.4  $10^3$ /uL

Abslt Cnt: Basophil: 0 - 0.2  $10^3$ /uL

Platelets: 140 - 415  $10^3$ /uL

Complex Metabolic Panel:

Glucose, Plasma: Fasting: 65 - 109 mg/dL

Glucose: 65 - 109 mg/dL

BUN (Blood Urea Nitrogen): 9 - 27 mg/dL

Creatinine: 0.5 - 1.5 mg/dL

BUN/Creat Ratio: 6 - 25

Uric Acid: Male Range 3.5 - 9.0 mg/dL

Uric Acid: Female Range 2.2 - 7.7 mg/dL

Sodium: 135 - 148 mmol/L

Potassium: 3.5 - 5.5 mmol/L

Chloride: 96 - 109 mmol/L

Carbon Dioxide: 20 - 32 mmol/L

Calcium: 8.5 - 10.6 mg/dL

Ionized Calcium: 3.5 - 5.2 mg/dL

Inorganic Phosphorus: 2.5 - 4.5 mg/dL

Total Protein: 6.0 - 8.5 g/dL

Albumin: 3.5 - 5.5 g/dL

Globulin: 2.2 - 4.1 g/dL

Albumin/Globulin Ratio: 0.9 - 2.0

Total Bilirubin: 0.1 - 1.2 mg/dL

Alkaline Phosphatase: 25 - 160 U/L

GGT (Gamma-Glutamyl Transferase): 0 - 85 U/L

LDH (Lactic Dehydrogenase): 0 - 240 U/L

SGOT (Serum Glutamic Oxaloacetic Transaminase):

0 - 45 U/L

SGPT (Serum Glutamic-Pyruvic Transaminase):

0 - 50 U/L

Serum Iron: 40 - 180 ug/dL

FSH: Pre-menopausal: 2.5 - 10.2 mIU/mL

Post-menopausal: 23.0 - 116.3 mIU/mL

Homocysteine: Normal: 5 - 15 umol/L

Optimal: Less than 10 umol/L

Thyroid Panel:

TSH (thyroid stimulating hormone): 0.4 - 5.5 mIU/L

Uptake (thyroid hormone uptake): 24 - 39%

T4 (thyroxine): 4.5 - 12.0 ug/dL

T7 (free thyroxine index): 1.4 - 4.9 U

## FIGURE 7Q

### **METABOLIC AND BIOCHEMICAL STUDIES** *continued*

#### **Recommendations**

These tests will assist your physician in better understanding your current health status. It is helpful to monitor and track changes over time, so periodic screening is recommended. Any abnormal results should be brought promptly to your physician's attention and reviewed in detail.

## FIGURE 7R

### **Consider A Program Of Regular Screenings**

While all medical specialists and organizations promote basic screening tests as a critical component of good preventive care, many differ about when and how often tests should be performed. Some organizations make recommendations based on the benefits of a test weighed against how much payers will have to pay for them.

You may prefer to be more assertive about your health. We recommend that you be screened annually to detect problems earlier and to have a point of reference in case you receive abnormal results in the future.

If you alter your diet, medication, exercise or lifestyle habits, or have medical complications, you may want to be checked more often to chart your progress. HealthScreen America is always ready to help you remain well informed about your health.

### **If This Is Ever A Concern**

If you have any questions or concerns about our tests your medical status, or wellness issues, we encourage you to speak with our Registered Nurse Educator.

If you are dissatisfied in any way or have any type of problem, we want to hear from you. Please write or call the Center Manager or our Client Advocate Director at 421-7777. You have our promise we will do everything possible to ensure you are happy with your HealthScreen America experience.

***\*\* Let us know if you would like information about our mobile screening units, available for screening events at your workplace, churches, community and civic organizations.***

## FIGURE 7S

### **Your Lifelong Health Record On The Web**

When you underwent your screening tests, you elected to keep a record of your results in the Lifelong Health Record on our website, [healthscreenamerica.com](http://healthscreenamerica.com). Here is the information you need to access your secure, confidential Lifelong Health Record:

Your Account Number:  
Your Registration Code:

Your screening test results have been posted in your own private file on our website and are ready for your use immediately. Just access [www.healthscreenamerica.com](http://www.healthscreenamerica.com). It's absolutely FREE.

HealthScreen America's Lifelong Health Record is much more than a place to safely and confidentially keep records of your screening tests. It is a comprehensive record of your health history. If you choose, this information can be available to others such as healthcare professionals in an emergency or family members who can help you. You can keep track of things such as:

- Medications you are taking or have taken in the past-and which ones worked best
- Your family's medical history
- Records of all your doctor and hospital visits
- Historical data like your blood pressure and cholesterol levels
- Allergies and reactions you've had
- Immunizations you've received
- Emergency medical information and contacts
- Your healthcare providers
- Where you get your prescriptions filled
- Which hospital you prefer
- Insurance information
- When you experienced certain symptoms
- And any other information you believe is important to your health

In addition, you can use the HealthScreen America website to:

- Look up in-depth medical information, from arthritis to wheezing
- Learn about your health risks through questionnaires
- Automatically receive important health reports
- Use interactive tools for enhancing your health

We encourage you to make frequent use of the wealth of information available to you at [healthscreenamerica.com](http://healthscreenamerica.com). It could be the most valuable health tool you've ever used-and it won't cost you a penny.

## FIGURE 7T

### PHYSICIAN'S REPORT

#### HealthScreen America Test Results For John Doe

This page contains a summary of screening tests completed for your patient by HealthScreen America. Tests were performed using state-of-the-art, FDA-approved technology operated by highly skilled health technologists, supervised by a board-certified physician.

At HealthScreen America, we strongly encourage each screening test participant to consider our services as part of an overall program of good health, to be undertaken in close cooperation and consultation with their personal physician.

If you would like more information regarding the testing protocols, testing technology or results, we encourage you to call HealthScreen America at 904-346-440. We welcome the opportunity to speak with you.

TEST	RESULTS	NORMAL RANGE
<b>BODY COMPOSITION</b>		
Height:	71	
Weight:	185 lbs	
Body Mass Index:	25.8 kg/m <sup>2</sup>	Normal: 18.5 - 24.9 kg/m <sup>2</sup>
Total Body Fat:	18 %	Women: 19% - 26% Men: 12% - 18%
<b>CARDIOVASCULAR</b>		
Blood Pressure:	125 /80 mm Hg	<130 / <85 mm Hg
Pulse (Heart Rate):	77 bpm	60 - 100 bpm
Total Cholesterol:	196 mg/dL	0 - 200 mg/dL
HDL:	45 mg/dL	35 - 150 mg/dL
Cholesterol/HDL Ratio:	3.0	1.0 - 4.5
LDL:	126 mg/dL	0 - 130 mg/dL
Triglycerides:	126 mg/dL	0 - 199 mg/dL
Arterial Elasticity:	45 pulse pressure	30-50
Ankle Brachial Index:		
Right Ankle	111 mm Hg	
Right Brachial	142 mm Hg	
Right ABI	1.28	Greater than 0.95
Left Ankle	109 mm Hg	
Left Brachial	130 mm Hg	
Left ABI	1.17	Greater than 0.95
Carotid Artery Scan:		
Right ICA Velocity:	45 cm / sec	< 110 cm/sec
Right CCA Velocity:	61 cm / sec	< 110 cm/sec
Right ICA/CCA Ratio:	0.74	< 1.8
Right Plaque Grade:	None/Minimal	None/Minimal
Left ICA Velocity:	46 cm / sec	< 110 cm/sec
Left CCA Velocity:	60 cm /sec	< 110 cm/sec
Left ICA/CCA Ratio:	0.77	< 1.8
Left Plaque Grade:	None/Minimal	None/Minimal



**FIGURE 7U**

TEST	RESULTS	NORMAL RANGE
Abdominal Aortic Aneurysm: Aortic Diameter: Comment:	1.8 cm	Less than 3 cm
<b>DIABETES</b> Blood Glucose	93 mg/dL	Less than 126 mg/dL
<b>OSTEOPOROSIS</b> T-Score	2.4 SD	Greater than -1.0 SD
<b>LUNG CAPACITY</b> FEV-1 FEV-1 % Predicted	3.24 75	Greater than 80% of predicted result
FVC FVC % Predicted	4.10 77	Greater than 80% of predicted result
<b>THYROID SCAN</b> Comments:	Normal	Negative

**Note:**

1. Metabolic and Biochemical studies are performed at a national reference laboratory and will be available within 7 days of visit.
2. CT results for cardiac calcification scores await review by a cardiologist and lung cancer screening will receive a radiologist's interpretation. These reports will be available under separate cover.

## FIGURE 7V

### John Doe's Personal Health Record

#### METABOLIC AND BIOCHEMICAL STUDIES

Several of the tests offered by HealthScreen America are sophisticated blood studies that require processing by an outside laboratory. These include:

- Tumor-marker tests such as CEA, CA-125 and PSA help identify cancer at an early stage
- Hormone studies such as the TSH, T4, FSH, testosterone and estrogen levels, hormone deficiencies or imbalances
- Hematologic studies that can uncover anemia or other problems involving your red cells, white cells and platelets
- Biochemical studies evaluate the health of vital organs such as the kidneys, liver, gallbladder and pancreas; also, electrolyte and chemical abnormalities can point to underlying disease
- Screening factors such as homocysteine levels are known to be associated with an increased risk of disease

These complex metabolic analyses do not lend themselves to simple discussion and explanation. Every test HealthScreen America performs is reported along with an expected normal range. The highest standards are used in these laboratory analyses. Nevertheless, no test can always be 100-percent reliable.

Test	Your Results	Normal Range
<b>Chemistry Studies:</b>		
BUN (Blood Urea Nitrogen):	14	9 - 27 mg/dL
BUN/Creat Ratio:	15.6	6 - 25
Potassium:	4.7	3.5 - 5.5 mmol/L
Carbon Dioxide:	27	20 - 32 mmol/L
Total Protein:	7.0	6.0 - 8.5 g/dL
Globulin:	3.2	2.2 - 4.1 g/dL
Total Bilirubin:	0.4	0.1 - 1.2 mg/dL
SGOT (Serum Glutamic Oxaloacetic Transaminase):	15	0 - 45 U/L
<b>Thyroid Studies:</b>		
Uptake (thyroid hormone uptake):	31	24 - 39%
T7 (free thyroxine index):	1.9	1.4 - 4.9 U

## FIGURE 7W

<b>METABOLIC AND BIOCHEMICAL STUDIES continued</b>		
<b>Hematology Studies:</b>		
RBC:	4.53	4.10 - 5.60 $10^3/\mu\text{L}$
Hct:	41.0	36.0 - 50.0%
MCH:	30.4	27.0 - 34.0 pg
Neutrophils:	65	40 - 74%
Monocytes:	6	4 - 13%
Basophils:	0	0 - 3%
Abslt Cnt: Lymphocyte:	2.5	1.0 - 4.8 $10^3/\mu\text{L}$
Abslt Cnt: Eosinophil:	0.2	0 - 0.4 $10^3/\mu\text{L}$
Platelets:	287	140 - 415 $10^3/\mu\text{L}$
<b>Lipid Studies:</b>		
Total Cholesterol	196	0 - 200 mg/dL
LDL	126	0 - 130 mg/dL
<b>Tumor Marker:</b>		
CEA:	0.5	0 - 5.0 ng/mL Smokers 0 - 3.0 ng/mL Non-Smokers
<b>Endocrine Studies:</b>		
Serum Iron:		40 - 180 ug/dL
<b>Prostate Specific Antigen:</b>		
PSA:	3.1	0 - 4 ng/ml

### Recommendations

These tests will assist your physician in better understanding your current health status. It is helpful to monitor and track changes over time, so periodic screening is recommended. Any abnormal results should be brought promptly to your physician's attention and reviewed in detail.

## Results Summary:

FIGURE 8A

### Percent of Population at Risk

	<u>Male</u>	<u>Female</u>
Abnormal Arterial Elasticity	54%	49%
Total Cholesterol	59%	57%
HDL	21%	2%
Moderate-Severe Plaque Grade	7%	6%
% Body Fat	88%	45%
BMI	86%	51%

# Participation

## Department

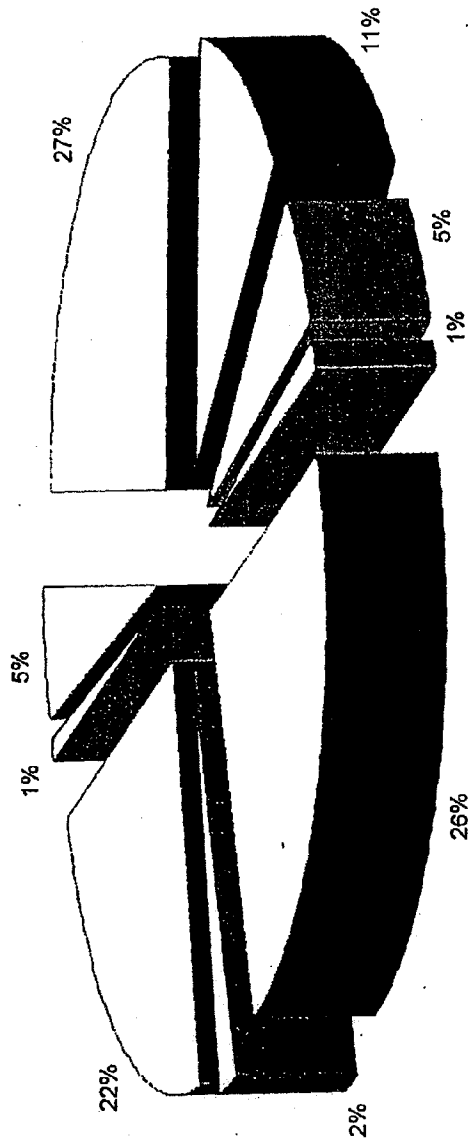
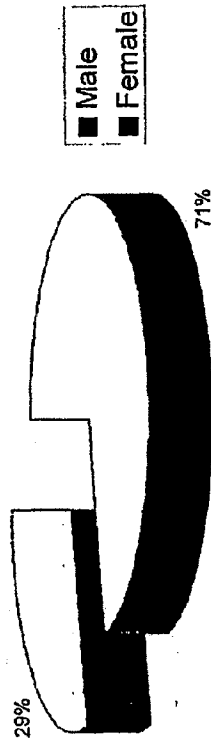


FIGURE 8B

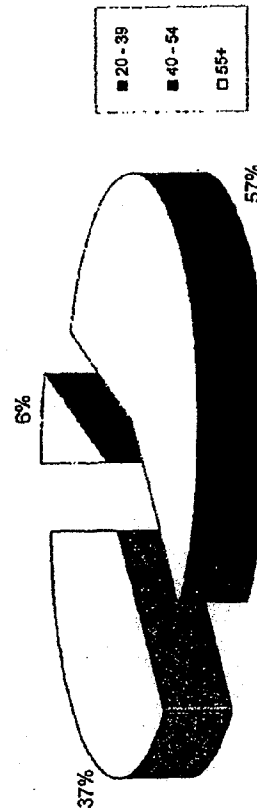
# Participation

FIGURE 8C

Gender

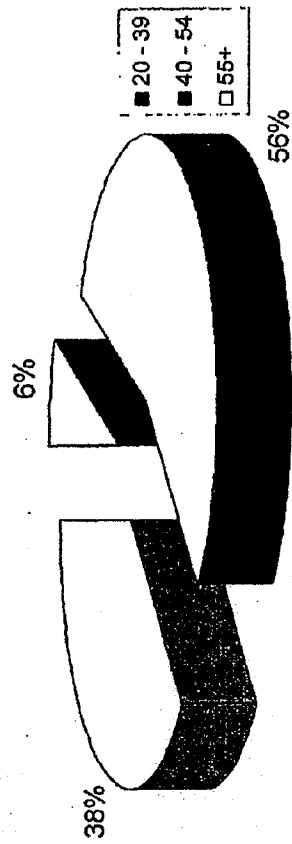


Age Groups



# Participation

Male



Female

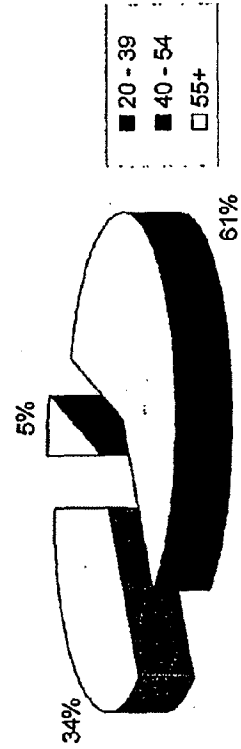
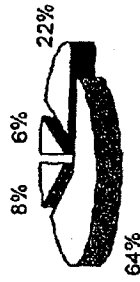
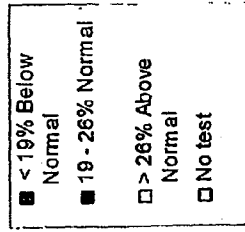


FIGURE 8D

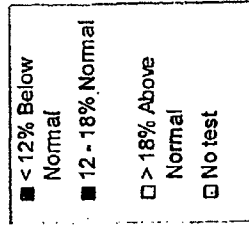
# Body Composition

## % Body Fat

Female



Male



## Body Mass Index

■ Female ■ Male

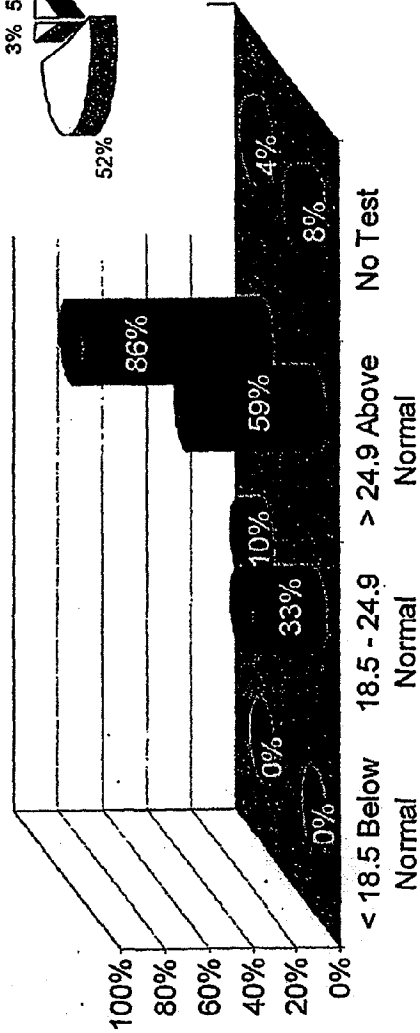
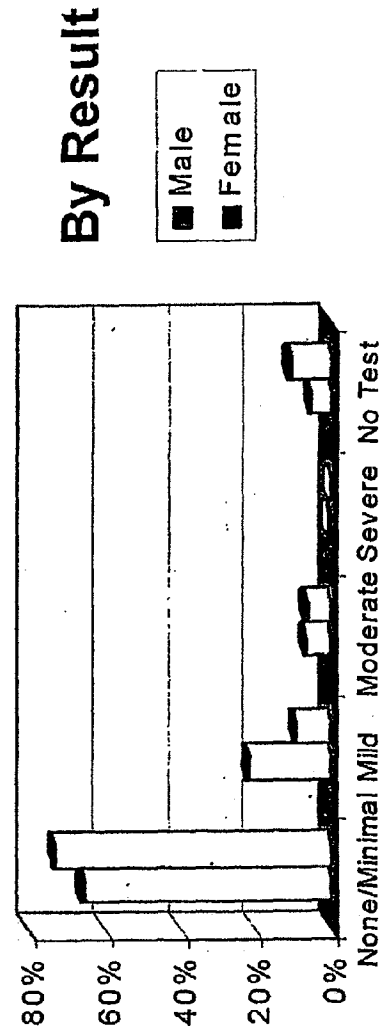
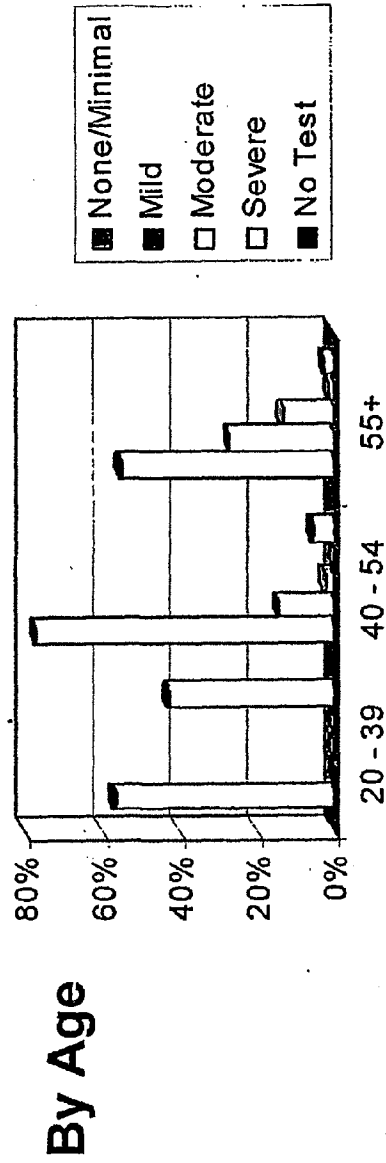


FIGURE 8E



# Carotid Plaque Grades

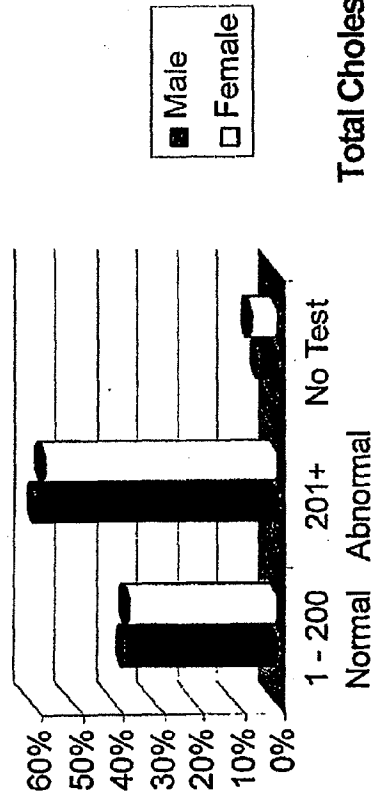
FIGURE 8F



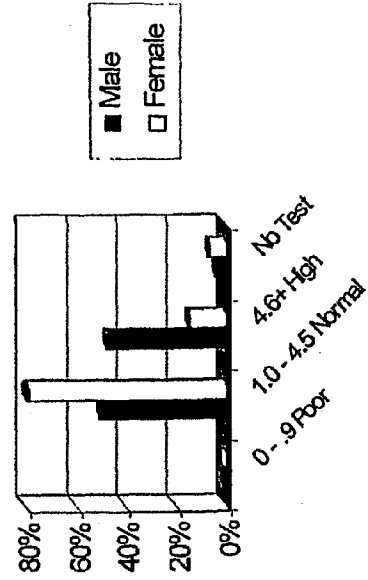
# Cholesterol

FIGURE 8G

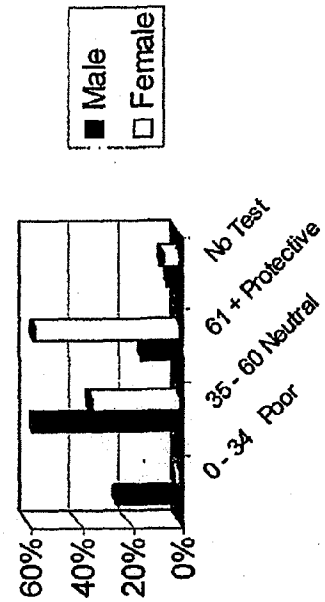
## Total Cholesterol



## Total Cholesterol/HDL Ratio



## HDL



**FIGURE 8H**

# Arterial Elasticity

## Pulse Pressure

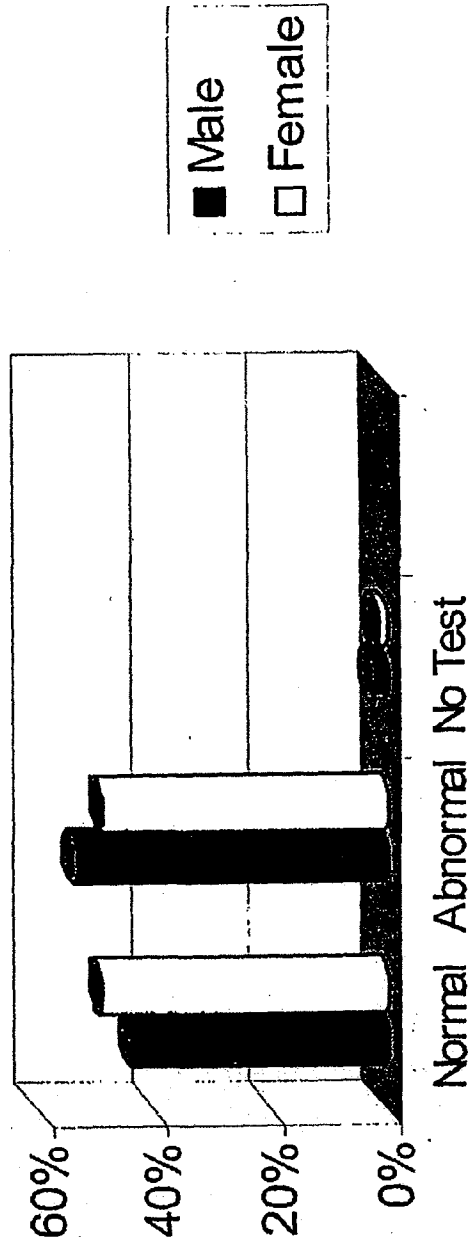


FIGURE 9

Business Source	No. Of Clients	Forecast Amt	% Tot Forecast	PreTaxPaid	% Tot Actual	Amt Diff
Billboard	4	\$1,783.70	0.83	\$2,216.10	0.96	\$432.40
Church/Community Center	10	\$2,626.00	1.22	\$2,774.00	1.21	\$148.00
Direct Mail	142	\$25,681.40	11.94	\$27,063.70	11.76	\$1,382.30
Don't Know	6	\$66.00	0.03	\$1,199.00	0.52	\$1,133.00
Friend	156	\$23,980.85	11.15	\$26,608.00	11.56	\$2,627.15
Informercial	28	\$10,347.10	4.81	\$11,157.00	4.85	\$809.90
Internet	12	\$4,461.00	2.07	\$5,168.00	2.25	\$707.00
Newspaper	225	\$73,607.11	34.21	\$75,897.80	32.98	\$2,290.69
Physician/Healthcare Professional	29	\$4,689.80	2.18	\$4,758.80	2.07	\$69.00
Public Event	243	\$9,541.60	4.43	\$9,600.50	4.17	\$58.90
Radio	10	\$858.00	0.40	\$862.00	0.37	\$4.00
Relative	56	\$10,611.70	4.93	\$11,062.70	4.81	\$451.00
Special Promotion	22	\$2,442.20	1.14	\$2,476.30	1.08	\$34.10
Television	165	\$28,788.10	13.38	\$31,346.00	13.62	\$2,557.90
Workplace	332	\$15,682.20	7.29	\$17,928.60	7.79	\$2,246.40
<b>Grand Total:</b>	<b>1,440</b>	<b>\$215,166.76</b>	<b>100.00</b>	<b>\$230,118.50</b>	<b>100.00</b>	<b>\$14,951.74</b>

**LifeLong  
Health Record**[Home](#) [Benefits](#) [Privacy](#) [Help](#)

It's free. It's easy. When you become a member of HealthScreen America's LifeLong Health Record you will be joining the growing number of people who want to access HealthScreen America's special services to stay informed and manage their health.

Items with a red \* are required for registration.

\*User Name:

Case sensitive, no special characters (#,\$,@,etc.)

\*Password:

Case sensitive, no special characters (#,\$,@,etc.)

\*Confirm Password:

Password Reminder:

\*Authorization ID:

An Authorization ID is required to view screenings.  
To receive an Authorization ID, call HealthScreen America's  
Customer Support at 1-904-877-SCREEN.

Cancel

Save



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**Figure 10A**

**HEARING**

Hearing is important to your general health status. Many daily activities are affected by decreased hearing including conversation, education, speaking on the telephone as well as driving a vehicle. Significant hearing loss may put you at increased risk of social isolation, anxiety and depression.

Your Results	Right Ear:	Left Ear:
1000 Hz:	Pass	Pass
2000 Hz:	Pass	Pass
4000 Hz:	Fail	Fail

The hearing screen is performed by presenting various frequencies to each ear at a loudness of 25 decibels (dB). Each pure tone is tested at 1000Hz, 2000Hz and 4000Hz. You should hear and respond to each separate frequency in order to "pass" that level. The failure to hear and respond will constitute a "fail" *unless you are over age 64*.

For persons aged 65 years and older, a 40-dB tone at 4000 Hz is recommended since high frequency hearing loss is common at this age. If you are over age 64 and hear the 40 dB tone your score will reflect that you "passed". About one in four individuals over age 65 will have some degree of hearing loss; of those with hearing loss, only about 10% who could benefit from a hearing aid actually use one.

A hearing screen can not only identify hearing loss, but also may serve to detect subtle problems that include allergies, eardrum damage and even certain forms of brain tumors.

The loss of hearing often occurs so gradually that you may be unaware of problems. In fact, others are much more likely to first notice it. You should consider a regular assessment of your hearing. If your hearing is not within the normal range, discuss this with your personal physician or a hearing and ear specialist.

**Testing Protocol:** The test is performed using a Maico MA 27 Audiometer by presenting you with different tones in each ear.

**Reference:** Clinician's Handbook of Preventative Services; National Library of Medicine — [www.nlm.nih.gov](http://www.nlm.nih.gov)

**Figure 10B**

**VISION**

Many individuals may be unaware of a gradual decrease in their vision. However, more than 90% of adults will eventually benefit from some form of corrective lenses or procedure. The visual acuity test is a useful screen for vision problems and can help determine if correction (with eyeglasses or contacts) or if further evaluation by an ophthalmologist is required. It also can indicate if more serious underlying eye conditions could be present. Some conditions could threaten possible permanent vision loss or even your overall health. In this test your vision is compared to what is typically readable at a distance of twenty feet. The result is expressed as a ratio.

**Your Results**

Right: 20/20/25 VA VA  
Left: 20/20/20 VA VA

**Normal Ranges**

20/20 VA  
20/20 VA

Loss of vision can be as simple as the need for corrective lenses, or may be due to an underlying medical condition such as diabetes. Common disorders affecting vision include cataracts, macular degeneration, glaucoma, and retinopathy. Poor vision in turn may contribute to accident, falls, isolation or depression.

If your results indicate you have less than normal vision, we recommend you seek further assessment from your doctor or an eye specialist. The American Academy of Ophthalmology recommends a comprehensive eye examination by an ophthalmologist every 1 to 3 years and at least annually for diabetics.

**Testing Protocol:** This test is performed using a CP-2 Everlight Projector Chart by Marco. The client reads projected images, one eye at a time.  
**Reference:** The American Academy of Ophthalmology and Clinician's Handbook of Preventive Services.

**Figure 10C**

**OXYGEN SATURATION**

This machine measures the amount of oxygen present in the bloodstream. Oxygen is required by every cell in the body and affects all chemical reactions that determine good health.

**Your Results**

Oxygen Saturation: 92 %%

**Normal Ranges**

Greater than 92%

This test is useful in providing information about problems relating to various types of lung diseases or heart failure.

If your results are abnormal, we recommend you see your physician who may want to conduct further testing such as a chest X-ray, spirometry or a CT scan.

**Testing Protocol:** Using a painless probe on the fingertip, this test is conducted with Welsh Allyn technology.  
**Reference:** American Lung Association – [www.lungusa.org](http://www.lungusa.org)

**Figure 10D**



**URINE ANALYSIS**

A urine specimen provides 10 results that are useful in evaluating a variety of conditions. Unfortunately, the urine analysis does not lend itself to a simple explanation. The result of any test alone is less meaningful. If you should have a test result that is outside of the normal range, do not be alarmed. This frequently occurs and may be of little significance. Your body is affected by many factors and your results can be subject to fluctuations and are never 100% accurate.

**Your Results**

Specific Gravity: 1.035  
pH: 8  
Leukocytes: ++  
Nitrite: Negative  
Protein: Trace  
Glucose: Normal  
Ketones: +  
Urobilinogen: ++  
Bilirubin: Negative  
Blood: Negative

**Normal Ranges**

1.005 - 1.025  
5 - 8  
Negative  
Negative  
Negative  
Normal  
Negative  
Negative  
Negative  
Negative

Abnormal results can provide information to detect conditions such as dehydration, urinary infection or inflammation, kidney stones, or tumors of the kidney or bladder.

If you have an abnormal score, we recommend you provide this information to your physician.

**Testing Protocol:** The client provides a urine specimen at the time of testing, which is analyzed using the Roche Urine Analyzer.  
**Reference:** Manual of Diagnostic and Laboratory Tests. Pagana KD & Pagana TJ 1998.

**Figure 10E**

## Figure 10F

### CT LUNG SCAN

#### Low Dose Spiral Lung CT:

Lung cancer is the most common form of cancer in the world. It also is the leading cause of cancer death for both men and women in America. There will be more than 160,000 new cases of lung cancer diagnosed this year. The vast majority, almost 90%, will be associated with smoking or a history of smoking in the past.

Tragically, the 5-year survival for these individuals diagnosed with lung cancer is only 12 to 14 percent. By the time symptoms appear or the individual feels ill, lung cancer is often far advanced. The diagnosis typically occurs too late for lung cancer to be effectively treated. Yet when detected early (in Stage 1) lung cancer survival rates are dramatically better, as high as 80 to 95 percent (5-year survival).

Early detection strategies are common for cancers of the breast, colon and prostate. Although lung cancer will kill more Americans than all of these types of cancer combined, no early detection strategy for lung cancer is widely utilized. Recent studies have shown that a low dose Spiral CT Lung Scan can detect four times the number of lung cancers as compared to traditional chest x-rays. Moreover, these cancers were six times more likely to be at the earliest stage (Stage 1) when the chances for cure are best. Although this new technique known as spiral or helical low dose CT scanning has been successful in detecting early lung cancers in smokers and former smokers. Whether this will actually save lives has not been proven and studies to answer this important question are in progress.

**You should be aware that the majority of nodules detected by a CT Lung Scan are benign and non-cancerous.** A nodule is especially likely to be benign if it is small (less than 5 mm in size), has smooth edges or has benign calcifications. Many nodules on review by a physician can be immediately be classified as benign and may not require further study. For example, the presence of calcium in a nodule on a high resolution CT can indicate a benign cause such as from an old infection. Even non-calcified nodules most often prove not to be cancer but this will require a physician's prudent judgment to manage these appropriately. Small nodules (less than 5 mm in size) may simply be followed with high resolution CT at 3, 6, 12 and 24 months to ensure that they do not change. The CT Lung Scan may also identify abnormalities of the lung tissue itself known as the lung "parenchyma". Changes in the lung parenchyma may be due to a variety of medical conditions such as emphysema or asthma.

Your personal physician can use the information gathered by a low dose CT Lung Scan to follow any abnormalities and take timely action when needed. One should realize that the best preventive measure is to not smoke or to quit as soon as possible. Also, no test can substitute the need for a careful examination and the expert advice of your physician.

**Testing Protocol:** The CT Lung Scan was performed on a GE helical high speed computed tomography scanner. A low dose lung protocol examines 10 millimeter sections through the lung fields. A registered radiologic technologist conducts the procedure. A radiologist reviews your CT images and the interpretation will be forwarded by mail. The radiologist is a highly trained physician who specializes in the interpretation of radiologic studies such as this one.

The low dose CT Lung Scan at HealthScreen America is painless, safe, rapid and cost effective. The actual procedure requires only 15 to 30 seconds and is a fraction of the cost of a traditional CT scan. The exam's x-ray exposure of only about that of two routine chest x-rays. Finally, there is no need to disrobe and no risk from medications or from intravenous contrast or needles.

**Reference:** Henschke CI, et al. Early Lung Cancer Action Project: overall design and findings from baseline screenings. *Lancet* 1999;354:99-105. American Cancer Society - [www.cancer.org](http://www.cancer.org)

## Figure 10G

### HEART CT SCAN

#### CT Heart Scan:

Coronary heart disease is the number one cause of death for both men and women in the United States. Millions of Americans have heart disease and don't know it. For many of these individuals the first and the last symptom they will experience will be death.

The hallmark of heart disease is the presence of plaque within the heart's arteries known as the "coronaries." The coronary arteries supply blood and oxygen to the heart itself. Plaque can build within these arteries when they are damaged by various factors such as high cholesterol, high blood pressure, diabetes or smoking. This process of plaque formation involves the deposition of fatty substances onto the arterial wall and is called "atherosclerosis".

As plaque builds up, it begins to harden and its calcium content gradually increases. Normal coronary arteries do not contain significant calcium, however those with hard and calcified plaque will have large amounts of extra calcium. Fortunately, the advanced helical CT Heart Scan is highly sensitive at detecting and measuring calcium and hard plaque within the heart arteries. It provides a "calcification" score that can help you and your physician predict possible future heart problems. The CT Heart Scan cardiac calcification score affords physicians the opportunity to detect atherosclerosis years before symptoms develop. Aggressive preventative measures then can be used to halt or even reverse atherosclerotic disease.

Normal Range	0	Risk of CVD* is less than 5%
	Low: 1-10	Risk of CVD* is less than 10%
	Mild: 11-100	Moderate risk, at least mild plaque burden
	Mod: 101-400	Moderate-High risk, at least moderate plaque burden
	Severe: Greater than 400	High risk of significant CVD*

\*CVD - Cardiovascular Disease

The cardiac calcification score has been shown to be an independent predictor of future cardiovascular events such as heart attack and stroke. It can identify an individual who has evidence of atherosclerotic disease. However, it is important to note that many cardiac tests such as a treadmill test only identify "obstructive" lesions. Obstruction of blood flow typically occurs when the artery is at least 70 percent blocked. Thus, many individuals with this disease are told they are "normal" when less than this level of blockage exists. Unfortunately, this only allows physicians to react to obstructive disease rather than preventing blockage from developing in the first place.

There are several factors known to increase the risk of coronary heart disease. These include high total cholesterol, high LDL, elevated triglycerides, low HDL, smoking, diabetes, high blood pressure, obesity, or a sedentary lifestyle. Yet having one of these risk factors does not guarantee the presence of heart disease. On the other hand, many individuals who die of coronary heart disease have none of these recognized risk factors.

The CT Heart Scan cardiac calcification score provides a non-invasive method of assessing atherosclerosis (or hardening of the arteries) in the heart arteries. It should be noted that this technology can not measure the amount of "soft plaque" in the arteries, which often is responsible for sudden, fatal heart attacks. With time, "soft plaque" becomes hard calcified plaque. Often people who have "hard plaque" also tend to have more of the "soft plaque." Thus, the cardiac calcium score is helpful in predicting the likelihood of future events such as heart attack or cardiac death.

Males over the age of 35 and females over the age of 40 with known risk factors or a family history of heart disease are the best candidates for a CT Heart Scan. The information gathered by the scan may change an individual's risk category in treatment guidelines, thus encouraging your physician to institute more aggressive prevention strategies.

## Figure 10H

### HEART CT SCAN cont.

#### How Do You Compare?

#### Findings from Measuring Cardiac Calcification Scores in 13,973 Men and 5,227 Women with No Symptoms

##### Men (13,973)

Percentile	Age						
	40 - 45	46 - 50	51 - 55	56 - 60	61 - 65	66 - 70	70+
10th	0	0	0	1	1	3	3
25th	0.5	1	2	5	12	30	65
50th	2	3	15	54	117	166	350
75th	11	36	110	229	386	538	844

##### Women (5,227)

Percentile	Age						
	40 - 45	46 - 50	51 - 55	56 - 60	61 - 65	66 - 70	70+
10th	0	0	0	0	0	0	0
25th	0.1	0.1	0.1	0.2	0.5	1	4
50th	0.1	0.1	1	1	3	25	51
75th	1	2	6	22	68	148	231

Reference: Janowitz WR, Agatston AS, Kaplan G, Viamonte M Jr. "Differences in Prevalence and Extent of Coronary Artery Calcium Detected by Ultrafast Computed Tomography in Asymptomatic Men and Women". *American Journal of Cardiology*, 1993;72:247-251.

It is important to note that a cardiac calcification score must be integrated into an individual's overall risk profile. Although the medical professionals at HealthScreen America can explain how your results compare to an average individual, your personal physician should guide your health management decisions.

If an elevated calcification score is found, then more aggressive therapy or further testing may be warranted. If calcium is not detected in the coronary circulation, this does not rule out the presence of atherosclerosis in the form of "soft plaque." However, a lack of calcium does imply a very low likelihood of significant obstruction.

For these reasons, the CT Heart Scan results should be used in tandem with other screening tests at HealthScreen America to identify the physical presence of abnormalities. Your physician will take each piece of information into consideration as "clues" when solving the overall "puzzle" of your health status.

**Testing Protocol:** Computed tomography of the heart is a simple, painless and rapid examination. There is no need to disrobe and no risk from medications, intravenous contrast or needles. The procedure takes a matter of minutes during which you lie on an open table-like platform. You should avoid caffeine, colas, coffee, nicotine, stimulants, decongestants or weight loss products in the four hours prior to your exam since a rapid pulse may interfere with the exam.

The scan uses ECG gating and an individual holding his breath to minimize motion. It produces approximately 40 images of the heart for the purposes of coronary artery calcium scoring. Post processing is performed on a 3 dimensional computer workstation to obtain the resting heart images, select areas of interest, determine the calcium score for each coronary artery and provide an assessment of the extent of atherosclerotic disease. Registered radiologic technologists conduct all examinations and board certified radiologists review all calcification scores.

Since the examination involves exposure to potentially harmful radiation, your informed consent is required. However, the level of radiation exposure is low. It is only about one third of that of an average coronary angiogram. Shielding of sensitive areas is typically not necessary, but is available upon request.

Reference: Rumberger JA, et al. Electron Beam Computed Tomographic Coronary Calcium Scanning: A Review and Guidelines for use in Asymptomatic Persons Mayo Clinic Proceedings 1999;74:243-252. Maher JE, et al. Progression of Coronary Artery Calcification. Mayo Clinic Proceedings 1999;74:347-355; American Heart Association - americanheart.org

Screening Date: 01/21/00  
Client Information: John Doe  
Date of Birth: 01/01/1955

## Figure 10I

### CT Heart Scan

#### Technique for Physicians:

A high-speed spiral CT of the heart is performed with EKG gating and suspended respiration. The examination is administered by registered radiologic technologists and board certified physicians review calcification scores. Scoring is performed using the Agatston method. Areas of the mediastinum, lungs, spine and abdomen are not adequately imaged and were not assessed in this study.

#### Coronary Arteries:

Your Results: 363

CORONARY	SCORE
Left Main Artery (LMA)	0
Left Anterior Descending (LAD)	358
Left Circumflex (LCX)	5
Right Coronary Artery (RCA)	0
Posterior Descending Artery (PDA)	0
Total CAC Score	363

If your score is 0: Absent calcium was not detected in the arteries of the heart. This does not absolutely exclude the presence of plaque. Non-calcified or "soft plaque" may be present and is not detected by this study. Your score does imply a very low likelihood of significant blockage within the coronary arteries.

**Risk Assessment:** There is a very low risk of cardiovascular disease. The probability of significant coronary heart disease is estimated to be less than 5% based on this cardiac calcification study.

#### Recommendations:

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.

If your score is 1 - 10: Calcium was detected with the coronary circulation and confirms the presence of at least mild atherosclerotic plaque. Non-calcified or "soft plaque" may also be present and is not detected by this study. The degree of cardiac calcification implies a low likelihood of significant obstructive lesions within the coronary arteries.

**Risk Assessment:** There is a low risk from cardiovascular disease based on this study. The probability of significant coronary heart disease is estimated to be less than 10% based on this cardiac calcification score.

#### Recommendations:

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.
2. Evaluation and control of modifiable risk factors is warranted.
3. Review this and all results with your primary care physician.

Screening Date: 01/21/00  
Client Information: John Doe  
Date of Birth: 01/01/1955

## Figure 10J

**If your score is 11-100:** Moderate calcium was detected and confirms the presence of moderate plaque. Non-calcified or "soft plaque" may also be present and is not detected by this study. The degree of cardiac calcification implies an increased risk for the development of significant lesions within the coronary arteries.

**Risk Assessment:** There is a moderate risk from cardiovascular disease based on this study. There is definite and at least mild plaque present within the coronary arteries based on this cardiac calcification study.

**Recommendations:**

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.
2. Evaluation and control of modifiable risk factors is warranted.
3. Your physician may consider primary prevention guidelines for cholesterol management and aspirin therapy.
4. Review this and all results with your primary care physician.

**If your score is 101 - 400:** High calcium was detected in the arteries of the heart and confirms the presence of a moderate to high degree of plaque. Non-calcified or "soft plaque" may also be present and is not detected by this study. The degree of cardiac calcification implies a definite increased risk for significant obstructive lesions within the coronary arteries.

**Risk Assessment:** There exists a moderate to high risk from cardiovascular disease based on this study. There is definite and moderate to high grade plaque present within the coronary arteries based on this cardiac calcification study.

**Recommendations:**

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.
2. Evaluation and control of modifiable risk factors is warranted.
3. Your physician may consider secondary prevention guidelines for cholesterol management and aspirin therapy.
4. Your physician may consider further testing to exclude silent ischemia.
5. Review this and all results with your primary care physician.
6. If you do not have a physician, we will work with you to find one.

**If your score is greater than 400:** Extensive calcium was detected with the coronary circulation and confirms the presence of an extensive degree of plaque. Non-calcified or "soft plaque" may also be present and is not detected by this study. The degree of cardiac calcification implies a definite risk of significant lesions within the coronary arteries. Extensive calcifications are often seen in individuals with an established history of heart disease.

**Risk Assessment:** There exists a high risk from cardiovascular disease based on this study. Definite and extensive plaque is present within the coronary arteries. There is a high likelihood (greater than 90%) of at least one significant obstructive lesion based on this study.

**Recommendations:**

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.
2. Evaluation and control of modifiable risk factors is warranted.
3. Your physician may consider secondary prevention guidelines for cholesterol management and aspirin therapy.
4. Your physician may consider further stress testing to exclude silent ischemia.
5. Review this and all results with your primary care physician.
6. If you do not have a physician we will work with you to find one.
7. Consultation with a cardiologist also may be prudent.

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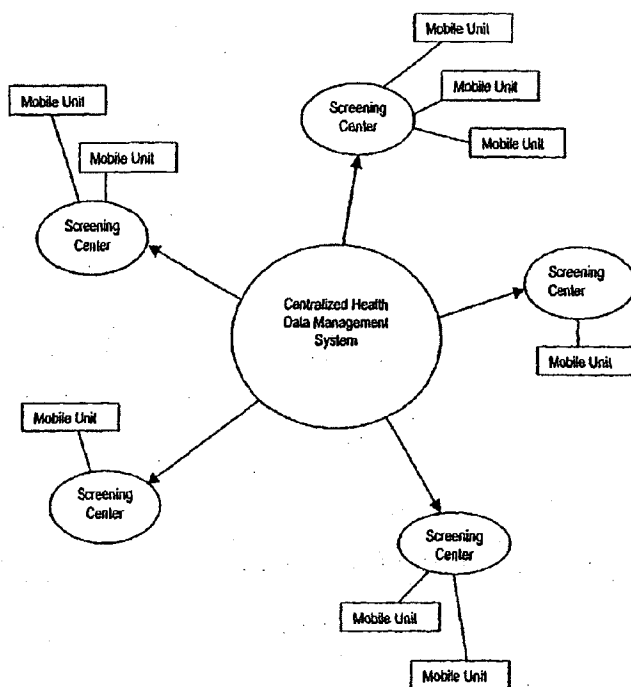
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(54) Title: METHOD FOR CENTRALIZED HEALTH DATA MANAGEMENT



(57) Abstract: A centralized health screening and data management system is provided. Specifically, the invention includes a method, system, and computer program for maintaining a centralized health screening and data management system in communication with a plurality of screening facilities, such screening facilities including mobile units for dispatch. The screening facilities (and mobile units) provide for collecting health data and conducting tests. The data and test results are transmitted to the centralized health screening and data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis.

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HEALTHSCREEN INTERNATIONAL INC.: "Healthscreenamerica.com announces "bricks and Mortar" addition" PRESS RELEASE, 'Online! 22 December 1999 (1999-12-22), XP002196378 Retrieved from the Internet: <URL:http://www.healthscreenamerica.com/AboutUs/PressReleases/ViewPress.asp?xmlfile=./xml/PR9912BricksAndMortar.xml> 'retrieved on 2002-04-16! the whole document	1-27
X	US 5 940 802 A (FRANSEN STEPHEN R ET AL) 17 August 1999 (1999-08-17) column 1, line 14 - line 23 column 5, line 10 -column 6, line 14 column 7, line 58 -column 8, line 20 --- -/--	1-27

☒ Further documents are listed in the continuation of box C.

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E	WO 01 29688 A (HANLON TERRENCE J O ;OSTERER MICHAEL F (US); BANDES ALAN S (US); 6) 26 April 2001 (2001-04-26)  page 9, line 2 - line 26 page 13, line 3 - line 9 figure 1 claims -----	1-3, 5-12, 15-17, 21-27

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US 5940802	A	17-08-1999	NONE	
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			JP 10124601 A	15-05-1998
			JP 10248817 A	22-09-1998
			EP 0958778 A1	24-11-1999
			US 6221009 B1	24-04-2001
			WO 9802086 A1	22-01-1998
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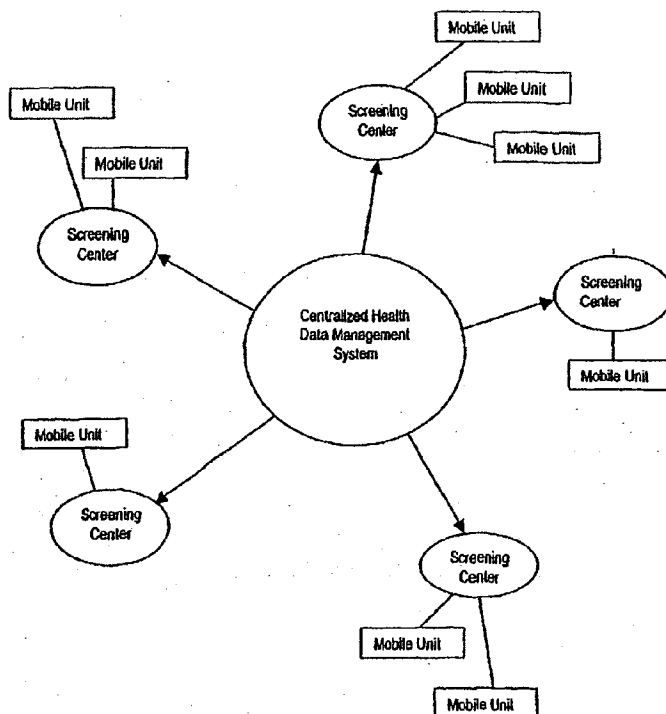
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(54) Title: METHOD FOR CENTRALIZED HEALTH DATA MANAGEMENT



(57) Abstract: A centralized health screening and data management system is provided. Specifically, the invention includes a method, system, and computer program for maintaining a centralized health screening and data management system in communication with a plurality of screening facilities, such screening facilities including mobile units for dispatch. The screening facilities (and mobile units) provide for collecting health data and conducting tests. The data and test results are transmitted to the centralized health screening and data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis.

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DESCRIPTIONMETHOD FOR CENTRALIZED  
HEALTH DATA MANAGEMENT

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Cross-Reference to Related Applications

This application claims priority from United States provisional application, serial number 60/184,961, filed February 25, 2000, and U.S. Patent Application Serial No. *not yet assigned*, filed February 23, 2001 under Attorney Docket Number HSA-101XC1 entitled "Method, System and Computer Program for Health Data Collection, Analysis, Report  
15 Generation, and Access," the disclosures of which are incorporated herein by reference in their entirety.

Technical Field

The present invention relates to centralized health screening and data management. Specifically, the invention relates to a method, system, and computer program for maintaining  
20 a centralized health screening and data management system in communication with a plurality of screening facilities, such screening facilities also having mobile units for dispatch. The screening facilities (and mobile units) provide for collecting health data and conducting tests. The data and test results are transmitted to the centralized health screening and data management system for analysis and storage in a manner that is accessible for report generation and aggregate  
25 information analysis.

Background Art

The diseases that kill most Americans are silent thieves, leaving few clues that they are robbing individuals of good health. By the time symptoms appear, the disease is often in an advanced, sometimes fatal, stage.

Heart disease is the number one killer of adults in America. While most heart patients have no warning prior to their first heart attack, the health community now recognizes that the buildup of plaque in coronary arteries is responsible for all heart attacks. Yet, plaque does not occur overnight. It builds up over time -- often as long as 10 to 20 years -- before becoming  
5 severe enough to block the coronary arteries, leading to a heart attack. Traditional stress tests detect plaque in very advanced stages, when there is more than 70% blockage. Yet, 68% of heart attacks occur when blockage is less than 50%. Early detection can lead to lifestyle changes and preventive treatment, saving lives and millions of dollars in intensive care treatment.

Cancer is the number two killer of adults in our country. Early detection often makes the  
10 difference between survival and fatality. Pre-cellular changes leading to cancer often occur in the body up to 10 years prior to the formation of a tumor. While early detection strategies are common for cancers of the breast, colon and prostate, no early detection strategy for lung cancer is widely utilized. Yet, lung cancer will kill more Americans than all of the above-mentioned cancers combined. Recent studies show the use of low-dose CT Scan can detect four times the  
15 number of lung cancers as compared to traditional chest x-rays. Moreover, these cancers are six times as likely to be discovered at the earliest stage (Stage 1) when the chances for a cure are best. Yet most insurance carriers do not cover the cost of early detection screening for lung cancer. While insurance companies may authorize chest x-rays, standard x-rays do not differentiate between irregular nodules less than two centimeters in the lungs. Detection when  
20 the nodule is less than two centimeters increases lung cancer survival rates from 20% to 80%. Again, early detection and accurate risk assessment can lead to preventive treatment and positive lifestyle changes for those not yet dealing with full-blown cancer. For those with malignant tumors, early detection while tumors are small and localized greatly increases survival rates and quality of life for those survivors.

25 "Despite a booming economy, lack of access to health care continues to be a problem in the United States. The number of individuals without health insurance has increased from 31 million in 1987 to more than 43 million in 1997, and over 70 million lacked insurance for at least one month between 1993 and 1996" (Qtd from Family & Community Health, Betsy Smith-Campbell, Apr. 1998). For millions of uninsured Americans, regular visits to physicians  
30 and routine screening tests are considered an expensive luxury, one that is often put off until debilitating symptoms appear. According to the Florida Health Association, research by the Kaiser Family/Commonwealth Fund Study revealed two out of every five uninsured Americans did not seek needed medical care in 1997. Too often, uninsured citizens do not receive any medical attention until they arrive at the hospital emergency room. By that time, care is reactive,

not preventive and the cost is far greater and treatment comes too late to ensure optimum life quality and longevity. For instance, a 52 year-old male presents at the emergency room with pain in his chest and running down his arm, shortness of breath and dizziness. He is experiencing a heart attack, and the treatment provided to him over the ensuing 24 hours could easily run over \$20,000. Had he been screened earlier with a CAT scan for his heart, ankle brachial test and cholesterol levels, he may have avoided the heart attack with some simple, life-style changes and relatively inexpensive medication, perhaps an aspirin a day.

Even those with insurance are not guaranteed access to medical screening tests that can save lives. Insurance companies, faced with exploding costs, feel a fiscal responsibility to wait for irrefutable proof that a particular screening test saves a substantial number of lives before authorizing its use. "There are 90 million smokers in this country. If they all want a CAT lung scan every year, it would cost \$400 each - and that's a big number," said Allan Kom, chief medical officer for Blue Cross/Blue Shield Association. "We're still studying whether it would make a difference in overall survival" (qtd. in USA Today, May 25, 2000). Typically, studies determining that level of proof take 10 to 15 years and are dependent upon funding to complete. In fact, NCI is beginning a 15-year study of 100,000 clinical trial subjects. Millions of individuals will die of lung cancer awaiting the results. Consumers, many of whom are aging baby-boomers, demand more control over their health care and more immediate access to potentially life-saving health screening.

In addition, our society is a mobile one. Families move an average of 8 times and no longer see the same general practitioner throughout their lives. Many adults travel on business and pleasure. There is a need for quick access to medical records should an emergency arise while away from home. Millions of Americans are covered under HMOs. If their primary care or specialty physicians leave the health care network, these consumers must transfer their records to newly-assigned physicians. Often transferring records involves a fee and an extended wait time, up to several weeks.

In addition, many physicians are compelled to get authorizations for most tests and may face stringent limitations when ordering tests. Asymptomatic patients are rarely given authorizations for many potentially life-saving screening tests.

All of these factors point to a pressing need for a system and method that encourages wellness care through affordable health screening tests available directly to consumers, secure storage of those tests' results, and lifelong storage of health records. Further, there is a need for immediate access of those records by the client and attending physician. There is a need for custom reports generated at the time tests are performed and additional reports generated as



needed. There is a need for an educational component to the reports that explains the results, the risk assessment, resources available to learn more and, possibly, lifestyle recommendations based on the results. An added benefit of this needed system, method and computer program is the compilation of tremendous data accumulated on a largely pre-symptomatic population. Such data can be used not only to analyze medical trends but can provide proof of the effectiveness of health screenings when accompanied by full explanations of the results and educational resources to learn more about potential conditions, prevention, wellness programs and treatment options. There is a need for a business process that maximizes the productivity of every component through efficient operations streamlined procedures to insure cost effectiveness while providing highly accurate, state of the art screening results.

While a number of patents have been issued dealing with more efficient gathering and dissemination of patient information, all have been solely for use by the medical community. Thus, the consumer does not experience greater control over individual health or a reduction in the cost of necessary, possibly life-saving screening tests. In addition, the medical databases used in the current processes are primarily built with data from symptomatic patients, rather than a population more reflective of the general population.

U.S. Patent # 6,014,630 to Jeacock & Nowak is comprised of a database system of various medical procedures, practices of individual physicians, methods followed by various medical facilities and a program to select desired ones for a particular patient with the capability of modification by the doctor. The program produces a personalized patient document that explains the procedure and follow-up care. While the document produced is educational for the patient, it is limited to one particular treatment by a specific doctor. The stated purpose is to protect the physician and facility from a malpractice suit due to lack of patient knowledge or understanding. It is not intended to increase a patient's control over health or to educate the patient on preventive care techniques to enhance wellness.

U.S. Patent # 6,151,581 to Kraftson, et al is for a system and method of collecting and populating a database with physician/patient data for processing to improve practice and quality healthcare. This invention seeks to build and administer a patient management and health care management database through the use of surveys to analyze the quality of care. While this invention seeks to improve patient care through the collection of data, the data relied upon is based solely upon a variety of surveys, thus is subjective rather than objective. It is also intended for the exclusive use of the medical community, not the individual consumer.

U.S. Patent #5,796,759 to Eisenberg, et al is for a system and method for assessing the medical risk of a given outcome for a patient. The method comprises obtaining test data from a

given patient corresponding to at least one test marker for predicting the medical risk of a patient and transforming the data with the variable to produce transformed data for each of the test markers. The transformed data is compared with the mean and standard deviation values to assess the likelihood of the given outcome for the given patient and the database is updated with the actual occurrence for the given patient, whereby the determined mean and standard deviation will be adjusted. The patent does provide a basis for risk assessment that is constantly updated as data changes. However, it is limited to already symptomatic patients undergoing treatment -- in this case, maternity patients. It provides a useful tool for the medical community regarding high-risk pregnancies but cannot be used to predict overall health trends among the general population. It also does not incorporate a program to educate the consumer or inform the consumer of possible preventive care or lifestyle changes to minimize risk.

US Patent #6,101,479 to Shaw is a system and method for allocating the resources of an organization. The method includes the steps of acquiring the information required to construct a model of the organization's primary processes as viewed from the perspective of a customer. The organization's resources are then allocated to the process whose improvement will have the greatest effect on customer-based performance measures of the organization. It provides a useful tool for implementing total quality control in a manner that has the greatest impact on a customer's perception of the organization. It does not implement quality control changes that enhance the overall effectiveness of the organization, including those areas beyond the customer's purview. It does not incorporate new strategies that ultimately benefit the consumer by maximizing efficiency to maintain reasonable costs while constantly striving for additional benefits and greater accuracy.

Medical screening can locate problems early so individuals can take appropriate action. However, the results of most lab reports are incomprehensible by most consumers and are often sent directly to doctors without even informing consumers of the results. Moreover, data from such screenings is often not collected, saved, analyzed or utilized by consumers, doctors, or research organizations which could benefit from such a-symptomatic health screening data and demographics associated therewith.

Therefore, there is a need in the art for a method by which consumers can take charge of their health. There is also a need in the art for consumers to be able to receive and comprehend data from their screenings and maintain such data as a life-long health record. There is a need for such a record to be readily accessed and updated. There is also a need for the ability to collect, analyze and maintain aggregate a-symptomatic health and demographic data for scientific research which may ultimately lead to the prevention and cure for disease.

### Brief Summary of the Invention

The present invention solves the above-stated problems in the art by providing method, system, and computer program for maintaining a centralized health screening and data management system in communication with a plurality of screening facilities, such screening facilities including mobile units for dispatch. The screening facilities (and mobile units) provide for collecting health data (e.g., demographic, diagnostic, screening). The data and screening test results are transmitted to the centralized health screening and data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis.

10 Features of the invention can be implemented in numerous ways, including as a system, a method, a computer site, or a computer readable medium. The invention preferably relies on a communications infrastructure, for example the Internet, wherein individual interaction is possible. Several embodiments of the invention are discussed below.

15 As a computer system, part of the invention generally includes a database and a processor unit. The processor unit operates to receive information (health, diagnostic, and demographic) about an individual and to analyze the received information in conjunction with the statistical/known information (e.g., disease symptoms, risk factors, blood studies, screening factors) to generate customized detailed reports both for the individual and his physician. The reports may include print or electronic media.

20 The printed report preferably includes results from the screening with analysis and recommendations, educational information, as well as a summary for the physician.

Part or all of the data can also be sent electronically or telephonically, with devices such as fax back, and maintained on a web server for confidential access with typical browsers. The data may be accessed or sent to medical practitioners or others at the discretion and direction of the consumer. The health and demographic data collected from the screening can pre-populate a life-long health record to avoid the need for the consumer to complete long medical information forms. The data may also be transmitted and viewed by other well known techniques such as email, interactive television, and the like. The computer site is preferably viewed with a client web browser as an HTML document through a web secure server communicating with an application server having a database associated therewith.

30 Screening test results may be used in conjunction with carefully formatted health risk assessment questionnaires which identify increased risks associated with social habits and behaviors as well as personal health history and familial history to better assess the individual

consumer's risk and identify whether that individual may qualify to participate in and benefit from a specific clinical study. In addition, the aggregate data can be used to forecast trends and evaluate medical probabilities based on a population that more closely matches the general population. Questions in the health risk assessment should be based upon findings from prior  
5 scientific studies such as the Framingham study and/or reliable sources recognized by the medical community such as the American Heart Association and the American Cancer Association.

As a computer readable medium containing program instructions for collecting, analyzing and generating output, an embodiment of the invention includes computer readable  
10 code devices for interacting with a consumer as noted above, processing that data in conjunction with analytical information, and generating unique printed or electronic media for that consumer.

As data is collected from individual consumers, the aggregate of information may also be maintained and utilized for scientific research and studies.

The advantages of the invention are numerous. First and foremost, the invention provides  
15 for a method by which consumers can take charge of their health, allowing them to receive and comprehend data from their screenings and maintain such data as a life-long health record. Linking the screening phase to the on-line health record provides the consumer with an easier means to begin and maintain such a health record by pre-populating a majority of the data fields from data already collected during the screening process. A resulting advantage is the ability to  
20 collect, analyze and maintain aggregate a-symptomatic health, diagnostic, and demographic data for scientific research.

Other aspects and advantages of the invention will become apparent from the following detailed description taken in conjunction with the accompanying drawings, illustrating by way of example the principles of the invention.

25 All patents, patent applications, provisional applications, and publications referred to or cited herein, or from which a claim for benefit of priority has been made, are incorporated herein by reference in their entirety to the extent they are not inconsistent with the explicit teachings of this specification. The following patents are incorporated herein by reference: U.S. Patent Nos. 6,192,416 to *Baxter*, 6,154,726 to *Rensimer*, 6,151,581 to *Kraftson*, 6,148,297 to  
30 *Swor*, 6,144,837 to *Quy*, 6,122,351 to *Schlueter*, 6,022,315 to *Iliff*, 6,018,713 to *Coli*, 6,017,307 to *Raines*, 6,016,497 to *Suver*, 6,014,630 to *Jeacock*, 6,014,626 to *Cohen*, 6,002,915 to *Shimizu*, 5,995,937 to *DeBusk*, 5,991,731 to *Colon*, 5,991,730 to *Lubin*, 5,987,434 to *Libman*, 5,941,820 to *Zimmerman*, 5,924,074 to *Evans*, 5,890,129 to *Spurgeon*, 5,796,759 to *Eisenberg*, and 4,315,309 to *Coli*.

### Brief Description of the Drawings

In order that the manner in which the above-recited and other advantages and objects of the invention are obtained, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. Understanding that these drawings depict only typical embodiments of the invention and are not therefore to be considered to be limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

Figure 1A is an overall system block diagram of a preferred embodiment of the present invention.

Figure 1B is a conceptual model of the centralized health screening and data management system of a preferred embodiment of the present invention.

Figure 1C is a conceptual model of the business model which shows the organizational and consumer relationships.

Figure 2 is a system flow diagram of a preferred embodiment of the present invention.

Figure 3 is a hardware diagram of a preferred embodiment of the present invention.

Figure 4 is an entity relationship model for a preferred embodiment of the present invention.

Figures 5A - 5B are flow charts of the operation of a preferred embodiment of the present invention.

Figures 6A - 6N are process and flow diagrams of a preferred embodiment of the present invention.

Figures 7A - 7W represent a sample client report generated by a preferred embodiment of the present invention.

Figures 8A - 8H represent a sample group summary report generated by a preferred embodiment of the present invention.

Figure 9 represents one sample aggregate information report generated by a preferred embodiment of the invention.

Figures 10A - 10J represent an additional sampling of test results generated by a preferred embodiment of the present invention and available for viewing and downloading from the online lifelong health record.

It should be understood that in certain situations for reasons of computational efficiency or ease of maintenance, the ordering of the blocks of the illustrated flow charts could be

rearranged or moved inside or outside of the illustrated loops by one skilled in the art. While the present invention will be described with reference to the details of the embodiments of the invention shown in the drawing, these details are not intended to limit the scope of the invention.

#### Detailed Disclosure of the Invention

5           Reference will now be made in detail to the embodiments consistent with the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numerals used throughout the drawings refer to the same or like parts.

          The present invention solves the problems in the art by providing a method, system, and computer program for maintaining a centralized health screening and data management system  
10   in communication with a plurality of screening facilities, such screening facilities including mobile units for dispatch. The screening facilities (and mobile units) provide for collecting data and conducting tests. The data and test results are transmitted to the centralized health data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis.

15           **Figure 1A** shows an overall system block diagram of a preferred embodiment of the present invention. Central to the health screening and data management system 10 is the Health Screening Information System (HSIS) 12 which is associated with a Health Screening Association (HSA) 14 to carry out the aspects of the present invention. The HSA may consist of various clinics, mobile units, screening facilities, and the like which provide for screening of  
20   clients, and collecting screening and demographic data therefrom. The HSA 14 communicates with the HSIS 12 for processing and analyzing the data. Custom reports are generated, both at the client level in the form of a client report 16 and at a collective level in the form of a group report 17. The system data is maintained in a database 18. This data may be accessed in aggregate form by various institutions and researchers 19 for scientific research. The system also  
25   provides for user access to electronic personal health records 20 via the Internet 22 or other electronic communication means (such as fax back system).

**Figure 1B** shows the relationships between the centralized health data management system with its associated remote screening centers (SC) and their respective mobile units. The preferred embodiment provides for a plurality of remotely located screening facilities and a  
30   centralized health data management system which communicates with each of the screening facilities. The screening facilities provide for (a) gathering information from a client, the information including demographic data, health data, and risk assessment data; (b) conducting a medical screening on the client (at least one test); (c) transmitting the information and results

to the centralized health data management system; and (d) generating a report for the client according to an analysis of the results taken in conjunction with the information provided by the health data management system. The screening facilities may also be referred to herein as screening centers (SC). The screening centers usually have associated therewith at least one mobile unit to dispatch to a remote location. The mobile units are configured specifically for each location for which said mobile unit is dispatched.

The screening center provides for replication of data in the mobile unit. The data received by the mobile unit is transmitted for storage in the centralized health data management system.

A brief overview of the system will now be described with reference to the process shown in Figure 2. Initially, demographic information is collected about the consumer in step 30. Health screening tests are also conducted to collect health data in step 32. Typical screening tests include, but are not limited to, ankle brachial index, abdominal aortic aneurysm, carotid ultrasound scan, thyroid ultrasound scan, osteoporosis screening, body composition, blood and pulse pressure, oxygen saturation, hearing screening, vision screening, urine analysis, blood studies (PSA, blood count, chemistry panel, lipid panel, triglycerides and risk ratio, thyroid blood test, C-reactive protein, fibrogen, homocysteine, CEA, CA-125), hormones, CT scans. This data, as well as other relevant data, is input into the system in step 34 manually or directly from the screening devices. The health, diagnostic, and demographic data is analyzed in step 36 in conjunction with known medical/statistical data (e.g., disease symptoms, risk factors, blood studies, screening factors). The system may utilize various algorithms, real-time learning and inference technology, profiling, pattern recognition learning algorithms, neural networks, and the like in order to correlate medical/statistical information with the collected data. The necessary medical/statistical information can be gathered from various known sources or acquired and continuously updated as the database acquires information from each new consumer.

After the analysis, the next step in the process is to generate in real-time a report for the individual consumer in step 37 (or for a group of consumers, e.g., a workplace). The personalized health record reviews individualized health risks and thoroughly explains test results with follow-up recommendations. Furthermore, a personalized health assessment is provided to determine further health risks.

The present invention also utilizes the consumer's information to pre-populate a "life-long health record" accessible on the Internet (or other communication means such as, but not limited to, a fax back system) in step 38. This record stores the test results, plus medical history including allergies, medications, immunizations, insurance and physician information. From this

site, consumers can store, retrieve and analyze personal medical data about themselves and their family in a secure environment. The site allows consumers to track their own health progress and tap into a huge library of medical information. Each time a consumer is screened, the results will be added to the site. The results may also be made available to consumers by other  
5 electronic communication means such as facsimile devices, e-mail, and the like.

The aggregate of collected information is also maintained on the centralized system. This information can be accessed in step 49 and utilized by doctors and researchers to discover trends, conduct scientific research, and study a-symptomatic health data.

**Figure 3** shows the preferred architecture of the present invention. The system  
10 comprises at least two networked computer processors (client component(s) for input and server component(s)) and a database(s) for storing data. The computer processors can be processors that are typically found in personal desktop computers (e.g., IBM, Dell, Macintosh), portable computers, mainframes, minicomputers, or other computing devices. Preferably in the networked client/server architecture of the present invention, a classic two or three tier client server model  
15 is utilized. Preferably, a relational database management system (RDMS), either as part of the Application Server component or as a separate component (RDB machine) provides the interface to the database.

In a preferred database-centric client/server architecture, the client application generally requests services from the application server which makes requests to the database (or the  
20 database server). The server(s) (e.g., either as part of the application server machine or a separate RDB/relational database machine) responds to the client's requests.

More specifically, the input client components are preferably complete, stand-alone personal computers offering a full range of power and features to run applications. The client component preferably operates under any operating system and includes communication means,  
25 input means, storage means, and display means. The user enters input commands into the computer processor through input means which could comprise a keyboard, mouse, or both. Alternatively, the input means could comprise any device used to transfer information or commands. The display comprises a computer monitor, television, LCD, LED, or any other means to convey information to the user. In a preferred embodiment, the user interface is a  
30 graphical user interface (GUI) written for web browser applications.

The server component(s) can be a personal computer, a minicomputer, or a mainframe and offers data management, information sharing between clients, network administration and security. The Database Server (RDBMS - Relational Database Management System) and the Application Server may be the same machine or different hosts if desired.



The present invention also envisions other computing arrangements for the client and server(s), including processing on a single machine such as a mainframe, a collection of machines, or other suitable means. The client and server machines work together to accomplish the processing of the present invention.

5       The database(s) is preferably connected to the database server component and can be any device which will hold data. For example, the database can consist of any type of magnetic or optical storing device for a computer (e.g., CDROM, internal hard drive, tape drive). The database can be located remote to the server component (with access via modem or leased line) or locally to the server component.

10       The database is preferably a relational database that is organized and accessed according to relationships between data items. The relational database would preferably consist of a plurality of tables (entities). The rows of a table represent records (collections of information about separate items) and the columns represent fields (particular attributes of a record). In its simplest conception, the relational database is a collection of data entries that "relate" to each other through at least one common field.

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#### *DESCRIPTION OF PREFERRED EMBODIMENT*

The following detailed description of the preferred embodiment presents a description of certain specific embodiments to assist in understanding the claims. However, one may practice the present invention in a multitude of different embodiments as defined and covered by the claims.

20

For convenience, the description comprises three sections: the overview and architecture of the concentric business method and apparatus; the process used with the individual consumer and the organization; and the storage of the demographic and screening information for analysis and report generation.

#### 25   I. OVERVIEW AND ARCHITECTURE OF THE CONCENTRIC BUSINESS METHOD AND APPARATUS

Health screening, offered directly to consumers without the need of a physician's referral or an insurance company's authorization, is at the center of the concentric business method, illustrated in **Figure 1C**. Appropriate screening tests for this business method are those not usually offered during an annual checkup unless symptoms are clearly present. The purpose is to offer tests to a largely a-symptomatic population in order to find and correct problems while the conditions are reversible before they may become chronic or fatal. In the preferred

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embodiment, screening tests are conducted with FDA approved, cutting-edge technology by experienced health professionals supervised by board-certified physicians. Tests may be designed to increase the comfort level of the client by ensuring as little discomfort as possible through painless non-invasive procedures that do not require disrobing to complete. Clients' comfort levels may further be raised through personal and immediate attention without the typical long waiting periods many people experience when completing physician ordered tests in other environments. In the preferred embodiment, patients are treated like preferred consumers whose time is valuable and right to know is paramount. Whenever tests do not require review by a certified physician, test results may be available immediately.

The health screening facility surrounds the consumer in the center of the concentric business method, acting as both a buffer zone and a facilitator between the consumer and the community at large, including the medical research community, the consumer's employer or potential employer and health care providers. The facility protects the consumer's privacy through careful storage in a database of screening test results and data, allowing access to the consumer's records only under the direction of the consumer and only in an anonymous manner that totally protects the consumer from any chance of personal information becoming public. At the same time, the facility matches helpful information, educational and clinical opportunities to the consumer, as long as the consumer permits the facility to do so, acting as a bridge between the medical community and the consumer. For instance, if the anonymous screening and assessment test results reveal a close fit for a clinical study, the facility provides information on the study to the consumer. If the consumer expresses interest in pursuing the opportunity, the facility would release the consumer's contact information to the researchers. Thus, the consumer experience has the optimum opportunity to benefit from cutting-edge medical advancements without endangering personal privacy.

The health screening facility is responsible for the process of storing test and health risk assessment results, **Figure 1C**. At the center of the architecture for this layer is a computer with sufficient space to create and maintain space required for storage of the demographic, diagnostic and screening data, multiple informational tables and educational information. Test results and pertinent information from the tables may be included in a client test result report as well as a variety of other reports issued upon request. A medical database is created on the host computer. The medical database is comprised of two databases: the primary, relational database and a subsidiary, hierarchical database that contains all the tables of information, including but not limited to normal ranges of test results and risk assessments. Accurate tables populated with the most current information available from the most reliable medical resources are essential. The

subsidiary database is more static and information is automatically pulled from there to populate specific fields in the reports generated in the primary database which operates in real-time.

In the preferred embodiment, the database script is written in SQL and the source code in Visual Basic, but they may be written in any combination of computer languages capable of  
5 creating both hierarchical and relational, object-oriented databases with communication embedded between them. Report software may also be utilized. In the preferred embodiment, Seagate Crystal Reports and Microsoft Excel are utilized, but any database management tool or system that is SQL compatible may be used including, but not limited to, Oracle and DB2. When  
10 information is pulled from SQL, it is put into Crystal Report for report generation and information analysis.

Additional workstations equipped with computers and printers may be used at point of service to enter demographic and screening data as well as generate appropriate reports, if desired. In the preferred embodiment, each computer at a permanent location has a shortcut on the desktop to the application that has a connection to the relational database. Computers in  
15 remote mobile units are preferably not connected to the primary database. Instead they are connected to a mobile server and use a merge replication to ensure autonomous function without a direct connection to the primary database. A production server is used for the permanent workstations.

In the preferred embodiment, mobile units may be transported any place in the world  
20 because each unit contains a mobile server and medical testing equipment, shipped in carefully-fitted rugged containers for safety and portability. To ensure efficiency, the mobile units would be transported from the permanent screening site closest to the health event. The preferred embodiment of this business model could include multiple health screening sites and one centrally located corporate headquarters, as illustrated in Figure 1B. The corporate  
25 headquarters would be the hub, providing the centralized health data management system which supports the screening facilities, which are the spokes in this analogy. The centralization of services in the health data management system, such as information technology, marketing, storage, analysis, and the like, provides maximum efficiency and cost containment, keeping the cost of health screening as reasonable as possible and therefore, affordable to a greater number  
30 of consumers.

Mobile units, located at the spokes (screening facilities) may be re-configured as the health event dictates so that only the medical testing equipment, server and portable workstations needed for that event are moved. Transportation may be by ground, air or sea as the metal containers meet all shipping requirements. Replication of data in mobile units ensures the data

can be accurately entered wherever the health event may be located. When merged, the data becomes part of the information in the relational database and it signals the subsidiary database, just as data entered from permanent locations does.

The mobile units may communicate with the HSIS in a number of ways. For example,  
5 there may be provided a method of propagating data throughout a computer system having mobile computers, and a computer server device at a fixed site (e.g., closest screening center), the method comprising providing relevant data at the computer server device to be transferred to the mobile computers, making a data exchange connection between a mobile computer and the computer server device when a mobile computer visits the site, providing software  
10 authorization checking when the data exchange connection is made to determine if the mobile computer is an authorized computer, conducting software checking to determine if relevant data resident in the computer server device is more recent than the relevant data in the mobile computer, invoking further software to transfer the relevant data from the computer server device to the computer if it is more recent than the relevant data in the mobile computer, and if the  
15 relevant data in the mobile computer is more recent than the relevant data in the computer server device, invoking further software to transfer the relevant data from the mobile computer to the computer server device, and repeating the process with further mobile computers when they visit the site whereby the relevant data can be propagated.

The subsidiary, hierarchical database is essentially a lookup database. In the preferred  
20 embodiment, List Manager is used. Hierarchical logic is incorporated in the program. The tables are composed of tasks, categories, tests, expected results, and the format of the expected results. Each test attribute has a unique identification number (ID#) which corresponds to the event in the List Manager.

Since the medical database contains consumers' health and information, strong security  
25 in the form of a firewall is used. In the preferred embodiment, further security protection is incorporated. For example, each client may be assigned an unique 14-digit identification number, rather than a more traceable identifier such as a Social Security number.

An Internet or business network (ITP connection) is used to support the database internally and an Internet web site accessible by all with several degrees of secured access is  
30 used to allow immediate, remote access to records and relevant educational information for both clients and physicians.

Because screening tests are offered directly to the consumer, educating the consumer to the availability and importance of early detection health screening is important. In the preferred embodiment, increasing consumer awareness is accomplished through a variety of methods,

including participation in community-sponsored health fairs, marketing strategies and educational as well as scheduling information available on the web site which hosts the life-long health record, an example of which is shown in **Figures 10A - 10J**.

## II. PROCESS USED WITH INDIVIDUAL CONSUMERS AND ORGANIZATIONS

5       **Figure 5A** is a flowchart showing the process for the individual with sub chart, **Figure 5B**, showing the process when an organization is sponsoring or hosting the health-screening event. Individual consumers call to obtain information and make an appointment. The individual's demographic data is entered into the database along with the time, date and location of appointment and the tests or test package desired. The cost is automatically figured and the  
10       appointment maker goes over the cost and any preparation needed, such as four hours of fasting for the glucose test. An alternative scheduling method could be offered at the web site wherein consumers could schedule appointments for health screening tests through a secured connection over the Internet.

**Figure 5B** starts with the booking of the event for the organization. All pertinent  
15       information is entered into the database, including time, date, location, tests or packages offered. Organizations can choose one package for each member or employee at a discounted fee or may choose to let their members or employees choose the tests desired. Responsibility for payment is also noted in the database as some business organizations fully cover the costs of the program for their employees under wellness plans. Health screenings can also be booked as events when  
20       a public organization, such as a local school or health department, wants to hold open house health fairs. Generally, no advance appointments may be needed when public organizations host health fairs. Types of tests given at health fairs may be limited to basics such as blood pressure, cholesterol readings, and vision/hearing screenings. Often, cost is nominal or free. In those cases, the event is entered into the database, so that data can be entered and tracked on the day of the  
25       event.

      Upon arrival at the location, both individuals and members of organizations are asked to sign consent forms. The consent forms preferably consist of four sections:

- (1) consent to take the tests;
- (2) consent to have the results posted on a secured, privacy-protected life-long health  
30       record accessible with a web browser;
- (3) consent to receive information in electronic and/or printed formats; and
- (4) consent to let their data be anonymously used in a statistical database to help forecast health trends and assess risk factors among a largely a-symptomatic population and to

be reviewed by a radiologist. The client may be informed those results will be sent within a few days.

For events hosted by businesses and organizations, an additional report may be generated which employers may use to design effective wellness programs for their employees, an example of which is shown in **Figures 8A - 8H**.

Part or all of the data can be sent electronically or telephonically, with devices such as fax back, and maintained on a web server for confidential access with typical browsers. The health and demographic data collected from the screening can pre-populate a life-long health record, which is an electronic health record which may be maintained and updated for a consumer. The life-long health record provides for viewing of the screening results electronically and for downloading for printing -- providing a complete report of the screening tests and health risk assessment results (an example of such a report is shown in **Figures 10A - 10J**). The life-long health record also provides for input screens for the consumer to add helpful information to complete the health history, from records of immunizations, medications previously or currently taken, and physician's contact information to search screens that allow the consumer to search for more information on a specific condition or to locate a new health care giver.

The data may also be viewed by other well-known techniques such as email, interactive television, and the like. The computer site is preferably viewed with a client web browser as an HTML document through a web secure server communicating with an application server having a database therewith. In the preferred embodiment, the client is assigned a password to use on the Internet web site which stores the test results, downloaded directly from the database. This allows immediate, secured access to the records by the consumer and appropriate physician. Additional reports can be printed and information can be updated to include other health records; however, no changes can be made to the test results. Other educational information can also be found on the web site and links are provided to additional helpful sites. Each time a client returns for additional testing, the database and lifelong health record on the web site are automatically updated through the database.

The web site may also be used by consumers who have not had any screening tests performed at the facility or mobile site. Health-related educational information, facility information, interactive quizzes and activities as well as links to other helpful health web sites may be incorporated. The web site may generate additional clients for the health screening tests and increase awareness of the need for early detection, thus generating more health screening

tests. This in turn increases the pool of statistics to be used for scientific analysis and appropriate candidates for clinical trials.

### III. STORAGE OF THE DEMOGRAPHIC AND SCREENING INFORMATION FOR ANALYSIS AND REPORT GENERATION

5           The database has three essential purposes. It stores individual data for consumers to allow them to have greater control over their health and well-being as well as greater, immediate access to their health records. Figures 7A - 7W is an example of a client report including a detachable section for the client's physician. The report gives comprehensive explanations of each test offered and charts which clearly show the normal ranges for each test. Preformatted and  
10       scripted, the report takes only a few minutes to print as the database pulls the information needed from List Manager and the results from the tests taken.

          Figures 8A - 8H illustrate an example of a printed Employer Summary Report, which could be issued after a health event held for a company. The medical facility operating this system, method and program may choose to give such a report to the organization, along with  
15       individual reports given only to the individual participants. The employer summary report provides documentation on the overall fitness of the staff, without releasing any private information. It explains each test given, including the possible reasons for the condition and the normal ranges. This example breaks down the overall results of the tests by gender in chart format, showing percentages of those within specific ranges. Recommendations for further  
20       medical care or lifestyle changes are also included. Such a report, in print or electronic media, can help the organization develop a wellness program that will benefit more of their employees because it pinpoints the greatest needs. In turn, healthier employees experience less absenteeism and the organization's productivity increases.

          As screening data is collected from individual consumers, the aggregate of information  
25       may also be maintained for scientific research. This invention amasses critical data on a largely a-symptomatic population by storing all the medical and demographic information without any personal identifiers. That information can help the medical community develop trend data and risk assessments on a far wider population than has generally been available before. Up until now, most databases have information on patients who already have symptoms, full-fledged  
30       diseases, or passed away. In some cases, determinations of risk are based on a population that is largely deceased. Yet, we all know that people are living longer and healthier lives today. At the same time, some risk factors have increased. For instance, the United States has a greater percentage of obese people than at any other time in the last century. Moreover, the fastest

be informed of clinical trials and experimental treatments that may pertain to them, according to their test results.

In the preferred embodiment, all four consents would be given, but clients are given the tests as long as they sign the first portion of the consent form. Information including which  
5 consents were given and the date signed is entered into the database prior to any tests being performed. As a safeguard, the program is designed to prevent any further action being taken until the consent information is entered. At the point the consent information is entered, the computer automatically assigns a unique identifier to the client. The use of this identifier increases security. Many consumers are concerned that insurance carriers or employers may use  
10 information about health risks to deny coverage or employment opportunities. Avoiding the use of easily traceable numbers, such as social security numbers, helps maintain the consumer's right to privacy. Each time a client comes in, the consent forms are reviewed, and any changes noted.

The client is taken to the testing area where the procedure is explained in detail by the technician. The test is performed and the data is entered into the database in the most error-free  
15 way possible. In the preferred embodiment, the data is not entered by data entry personnel but by direct entry from the equipment or a smart card-type device. To further increase accuracy, additional accuracy checks may be instituted on a regular basis. For instance, another member of the facility staff not involved with the consumer's screening test may review the test results to certify that the results were entered correctly. In the preferred embodiment, two additional  
20 accuracy checks are routinely made to ensure the data is correct to the greatest degree possible. Such direct entry and accuracy checks avoid the risk of human error, such as reversing digits, and ensures a higher degree of accuracy.

Once all tests are completed, the client may be given a report, an example of which is shown in **Figures 7A - 7W**. The printed report preferably includes results from the screening  
25 with analysis and recommendations well as a summary for the physician. For example, the suggestion to eat a low fat diet and increase exercise could be passed on from the American Heart Association to a client with high body fat content and high cholesterol levels. In the preferred embodiment, only suggestions and recommendations widely accepted by the medical community and supported by well-respected authorities in the field, such as the American  
30 Diabetes Association, are made to consumers. However, under circumstances in which this invention is practiced by the consumer's personal physician, the preferred embodiment could include additional recommendations. The only test results that could not be included on the immediate report are those requiring medical review, such as the CT lung scan which needs to



be reviewed by a radiologist. The client may be informed those results will be sent within a few days.

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          As screening data is collected from individual consumers, the aggregate of information  
25       may also be maintained for scientific research. This invention amasses critical data on a largely a-symptomatic population by storing all the medical and demographic information without any personal identifiers. That information can help the medical community develop trend data and risk assessments on a far wider population than has generally been available before. Up until now, most databases have information on patients who already have symptoms, full-fledged  
30       diseases, or passed away. In some cases, determinations of risk are based on a population that is largely deceased. Yet, we all know that people are living longer and healthier lives today. At the same time, some risk factors have increased. For instance, the United States has a greater percentage of obese people than at any other time in the last century. Moreover, the fastest

growing segment of obesity is found in the under 21 population. If new ways of combating obesity are not discovered through scientific research and clinical trials, the United States could be looking at far greater instances of obesity -related disease in the next 20-40 years. Having more current information available to the medical community can translate into tremendous leaps  
5 forward in preventive care and early intervention.

Reports can be generated that detail risks according to location, age, gender and specific medical factors. Medical personnel can use that information to populate clinical trials with a cross-section of people at increased risk. To date, most clinical trials for preventive care rely upon advertising to the public in hopes of getting responses from those who are at greater risk.  
10 For instance, a large Tomaxofen study advertised for women who have had some family history of breast cancer. Researchers were forced to rely upon the accuracy of the women's memories, and, in some cases, stories repeated by family members but not experienced by the women, themselves, when choosing candidates for the study. With this invention, researchers will be able to choose candidates whose DNA contains the specific gene related to increased risk of breast  
15 cancer.

A clinical trial based upon known evidence of risk factors could prove invaluable and produce more accurate results. For example, a clinical trial could use the more concrete criteria of at least 30% but not more than 45% calcified plaque in the coronary arteries to test medication for the prevention of heart attack. The database would generate a report based on the health  
20 screening of those participants who authorized information be released for clinical trials, and those people could be contacted directly by the medical personnel running the trial.

In addition, other reports can be generated, from those that show the source of business for the health-screening center (Figure 9) to those that delineate overall results from all participants by test. Results of these reports can be used to pinpoint areas or groups of people  
25 who may need further education about the importance of early detection and preventive care in addition to business forecasting. Custom reports can list the normal, abnormal and total for each test for a specific period of time or the abnormal result percentage for each test. This data can be used for trending forecasts and immediate risk assessments.

Accordingly, the advantages of the present invention are numerous. For example, the  
30 knowledge that consumers can take part in comprehensive health screening without incurring penalties from their insurance companies or employers frees consumers to become better informed and armed to fight off disease through early intervention. Viewing and fully understanding concrete test results often provides the needed catalyst to seek treatment and/or make positive lifestyle changes. Being able to access the reports immediately through the

Internet provides a greater measure of security while traveling, if a medical emergency should arise. Immediate accessibility to the client's lifelong health record also makes changing doctors or seeking second opinions easier and faster than waiting for medical records from a physician's office. Automatic updating of the records every time health screening tests are taken provides  
5 a complete, convenient record that may span most of the consumer's lifetime, creating a more thorough record than is generally available. The additional information the consumer may add, such as the results of physician ordered tests or a record of medicine taken and any adverse effects could prove invaluable.

Although the invention has been described with respect to a health screening model, it  
10 is contemplated that other industries which utilize a centralized data management system with screening facilities may come within the scope of this invention as applicable.

Based on the foregoing specification, the invention may be implemented using computer programming or engineering techniques including computer software, firmware, hardware or any combination or subset thereof. Any such resulting program, having computer-readable code  
15 means, may be embodied or provided within one or more computer-readable media, thereby making a computer program product, i.e., an article of manufacture, according to the invention. The computer readable media may be, for instance, a fixed (hard) drive, diskette, optical disk, magnetic tape, semiconductor memory such as read-only memory (ROM), etc., or any transmitting/receiving medium such as the Internet or other communication network or link. The  
20 article of manufacture containing the computer code may be made and/or used by executing the code directly from one medium, by copying the code from one medium to another medium, or by transmitting the code over a network.

One skilled in the art of computer science will easily be able to combine the software created as described with appropriate general purpose or special purpose computer hardware to  
25 create a computer system or computer sub-system embodying the method of the invention. An apparatus for making, using or selling the invention may be one or more processing systems including, but not limited to, a central processing unit (CPU), memory, storage devices, communication links and devices, servers, I/O devices, or any sub-components of one or more processing systems, including software, firmware, hardware or any combination or subset  
30 thereof, which embody the invention. User input may be received from the keyboard, mouse, pen, voice, touch screen, or any other means by which a human can input data into a computer, including through other programs such as application programs.

It should be understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be

suggested to persons skilled in the art and are to be included within the spirit and purview of the claims.

## CLAIMS

What is claimed is:

- 1           1. A method for centralized health screening and data mangement comprising:
  - 2           a) providing a plurality of remotely located screening units;
  - 3           b) providing a centralized health data management system; and
  - 4           c) enabling data communication between the centralized health data management system
  - 5       and each of the screening units, wherein each of the screening units provides for:
    - 6           i) gathering information from a client, said information comprising demographic data,
    - 7       health data, and risk assessment data;
    - 8           ii) conducting a medical screening on the client, wherein said screening comprises at
    - 9       least one test;
    - 10          iii) transmitting said information and results from said at least one test to said centralized
    - 11       health data management system; and
    - 12          iv) generating a report for the client according to an analysis of the results taken in
    - 13       conjunction with said information provided by said health data management system.
- 1           2. The method of claim 1 wherein said remotely located screening units comprise
- 2       screening centers.
- 1           3. The method of claim 2 wherein said screening centers comprise at least one mobile
- 2       unit associated therewith, wherein said screening center dispatches said mobile unit to a remote
- 3       location.
- 1           4. The method of claim 3 wherein said mobile units are configured specifically for each
- 2       location for which said mobile unit is dispatched.
- 1           5. The method of claim 3 wherein said screening center provides for replication of data
- 2       in said mobile unit.

1           6. The method of claim 3 wherein data received by said mobile unit is transmitted for  
2 storage in said centralized health data management system.

1           7. The method of claim 1 wherein risk assessment data is gathered from the client by  
2 utilizing a predetermined series of questions designed to elicit data associated with a plurality  
3 of risk factors.

1           8. The method of claim 1 wherein the step of conducting medical screening on the client  
2 comprises:

3           assigning a unique client identifier to the client;  
4           assigning a unique screening identifier for said medical screening;  
5           associating said client identifier with said screening identifier;  
6           recording start time of said screening;  
7           conducting at least one test; and  
8           recording end time of said screening.

1           9. The method of claim 8 further comprising:

2           storing said information and results from said at least one test in a database associated  
3 with said centralized health data management system;

4           associating a unique test identifier for each test taken by the client with said client  
5 identifier; and

6           assigning a unique results identifier, said results identifier associated with said client  
7 identifier.

1           10. The method of claim 7 wherein said analysis of the results taken in conjunction with  
2 said information provided by said health data management system comprises, for each of a  
3 plurality of risk factors,

4           a) assigning unique identifier for each risk factor,

5           b) analyzing said risk assessment data; and

6           c) determining a risk indication for the client for each risk factor.

1           11. The method of claim 10 wherein said risk indication is a positive or negative  
2 indicator.

1           12. The method of claim 10 further comprising considering a client's age category in  
2 determining said risk indication.

1           13. The method of claim 10 further comprising considering a client's gender in  
2 determining said risk indication.

1           14. The method of claim 10 further comprising considering a client's race in determining  
2 said risk indication.

1           15. The method of claim 1 wherein the report generated for the client according to said  
2 analysis comprises:  
3           a screening summary comprising test name, client results, and normal ranges;  
4           a detailed report comprising educational information for each of said tests conducted  
5 during client screening, said educational information comprising test name, client results, normal  
6 ranges, associated health risks, recommendations, and test protocols; and  
7           a physician's report comprising test name, client results, and normal ranges.

1           16. The method of claim 1 further comprising pre-populating an electronic health record  
2 for remote access by the client.

1           17. The method of claim 16 wherein the step of populating an electronic health record  
2 for remote access by the client comprises:  
3           establishing a remotely accessible secure file for said client;  
4           storing demographic information collected from said client;  
5           storing test results for said client for each screening;  
6           allowing client to update file with additional data;  
7           allowing client to control access to data by others.



1           18. The method of claim 1 wherein said steps are performed for each of a plurality of  
2 clients in an organization wherein said organization has assigned thereto a unique organization  
3 identifier and said organization identifier is associated with each client who is a member of the  
4 organization.

1           19. The method of claim 18 further comprising assigning a unique department identifier  
2 for each department in said organization wherein said department identifier is associated with  
3 each client who is a member of the department.

1           20. The method of claim 18 further comprising generating an organization report, said  
2 organization report comprising:  
3           results summary showing percent of organization at risk for at least one category of  
4 health risks;  
5           participation percentages by department, age groups, gender, and sex; and  
6           detailed reports showing levels of risk by percentage of clients in each category.

1           21. The method of claim 1 further comprising combining the results of a plurality of  
2 clients in a database of said centralized health management system to provide aggregate  
3 information and providing access to said aggregate information.

1           22. A system for centralized health data management, comprising:  
2 a centralized health data management system;  
3 a plurality of remotely located screening units, each of said screening units comprising:  
4           (a) input means for gathering information from a client, said information  
5 comprising demographic data, health data, and risk assessment data;  
6           (b) screening devices for administering a medical screening on the client,  
7 wherein said screening comprises at least one test;  
8           (c) communication means for transmitting said information and results from said  
9 at least one test to said centralized health data management system; and  
10           (d) output means for generating a report for the client according to an analysis  
11 of the results taken in conjunction with said information provided by said health data  
12 management system.

1           23. The system of claim 22 wherein said centralized health data management system  
2 comprises processing means for analyzing results in conjunction with risk factors associated with  
3 the client and pre-populating an electronic health record for remote access by the client.

1           24. In a centralized health data management system having a plurality of remote  
2 screening units communicating therewith, a computer readable media containing program  
3 instructions for outputting data from a computer system, the data being obtained from tables in  
4 a database associated with the centralized health data management system, said computer  
5 readable media comprising:

6           first computer program code in each of said remote screening units for gathering  
7 information from a client, said information comprising demographic data, health data, and risk  
8 assessment data;

9           second computer program code in each of said remote screening units for recording the  
10 results of a medical screening administered to the client, wherein said screening comprises at  
11 least one test;

12          third computer program code in each of said remote screening units for transmitting said  
13 information and results to a centralized health data management system;

14          fourth computer program code in said centralized health data management system for  
15 analyzing results in conjunction with risk factors associated with the client; and

16          fifth computer program code for generating a report for the client according to an  
17 analysis of the results taken in conjunction with said information.

1           25. A centralized system for storing and retrieving health data from a plurality of remote  
2 screening units comprising:

3           a relational database for storing data comprising a plurality of interrelated tables wherein  
4 each table comprises an attribute having a common domain with an attribute of at least one other  
5 table in the database; and

6           means for collecting and storing demographic information from a client in said database,  
7 the client having assigned thereto a unique client identifier;

8           means for conducting a medical screening on the client at each of said remote screening  
9 units, wherein said screening comprises at least one test;

10          means for storing results from said at least one test in said database;

11          means for analyzing results in conjunction with risk factors associated with the client;

12          and

13 means for generating a report for the client according to said analysis on the basis of the  
14 data stored in the relational database.

1 26. The system of claim 25 further comprising means for pre-populating an electronic  
2 health record for remote access by the client.

1 27. The system of claim 25 further comprising a plurality of dispatchable mobile units  
2 associated with said remote screening units, said mobile units selectively configured to provide  
3 means for collecting and storing demographic information from a client in said database and  
4 means for conducting a medical screening on the client.  
5

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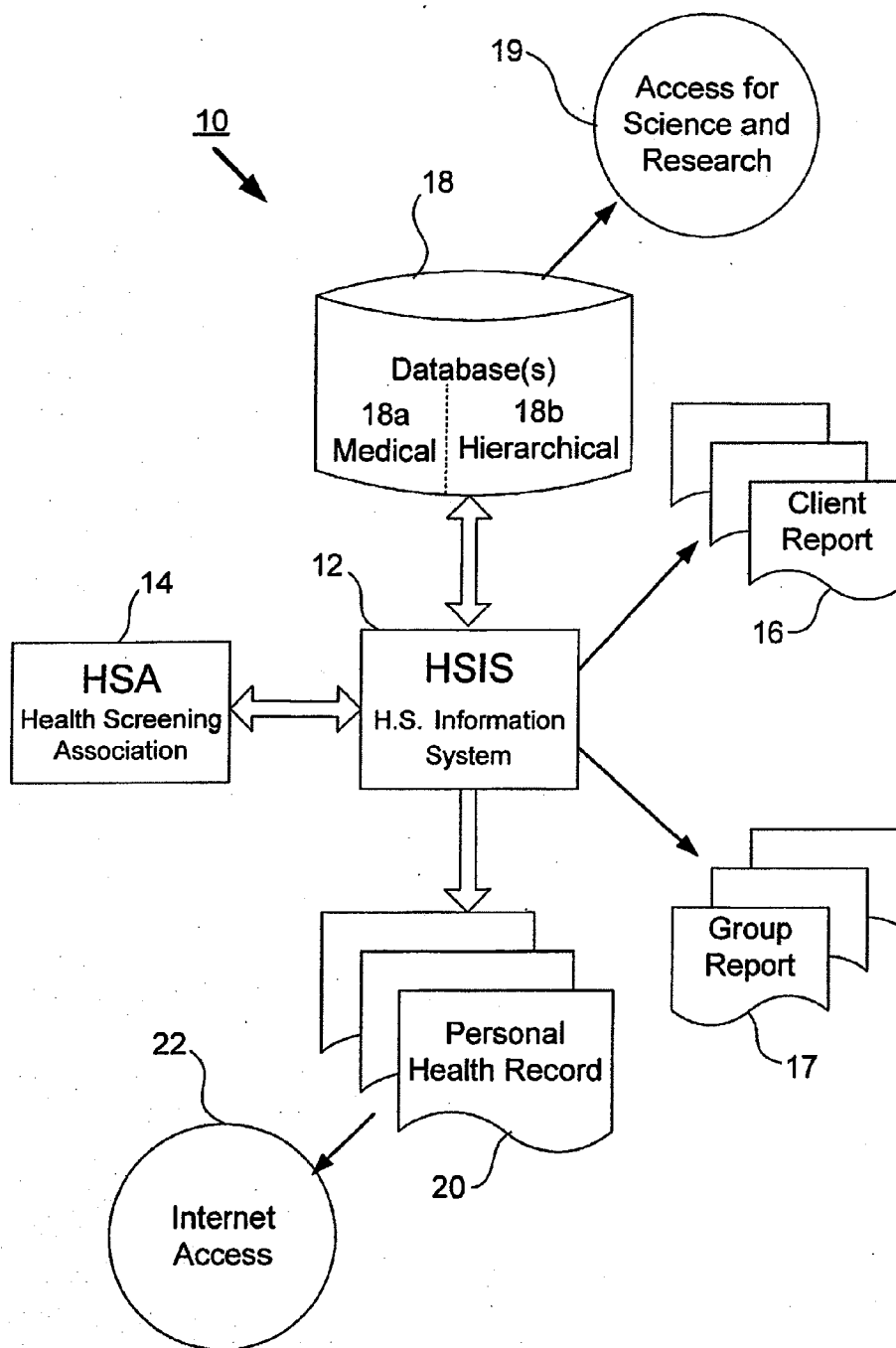


FIG. 1A

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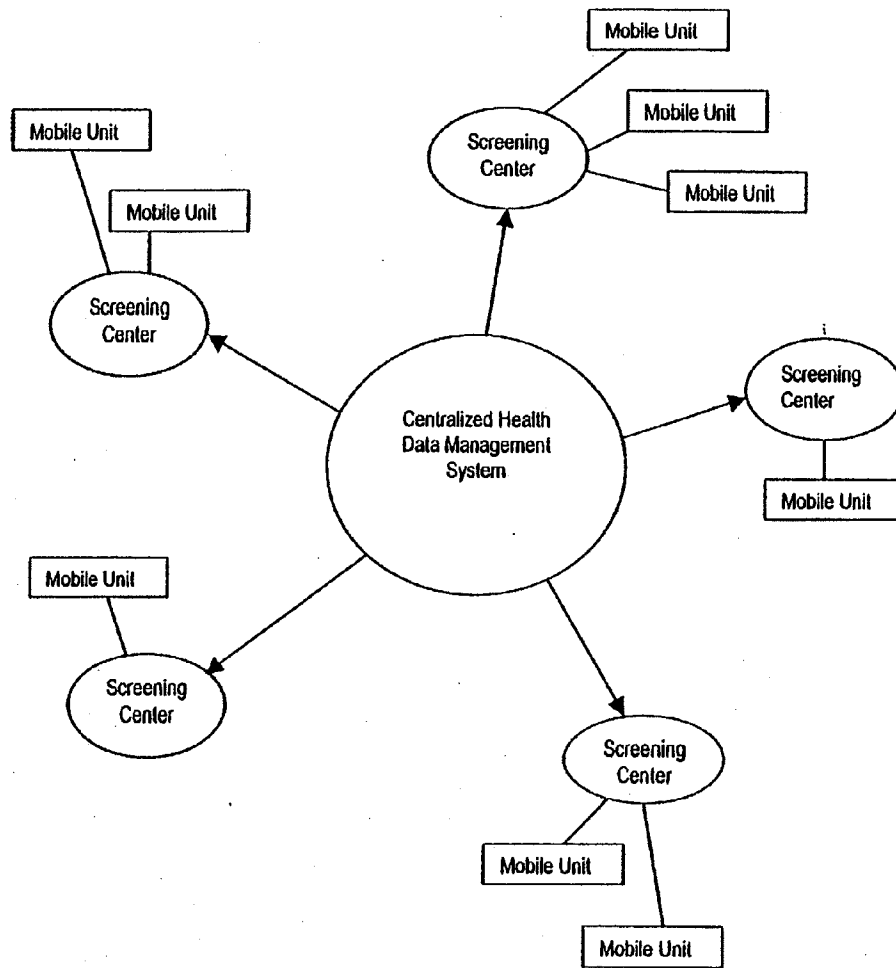


FIG. 1B

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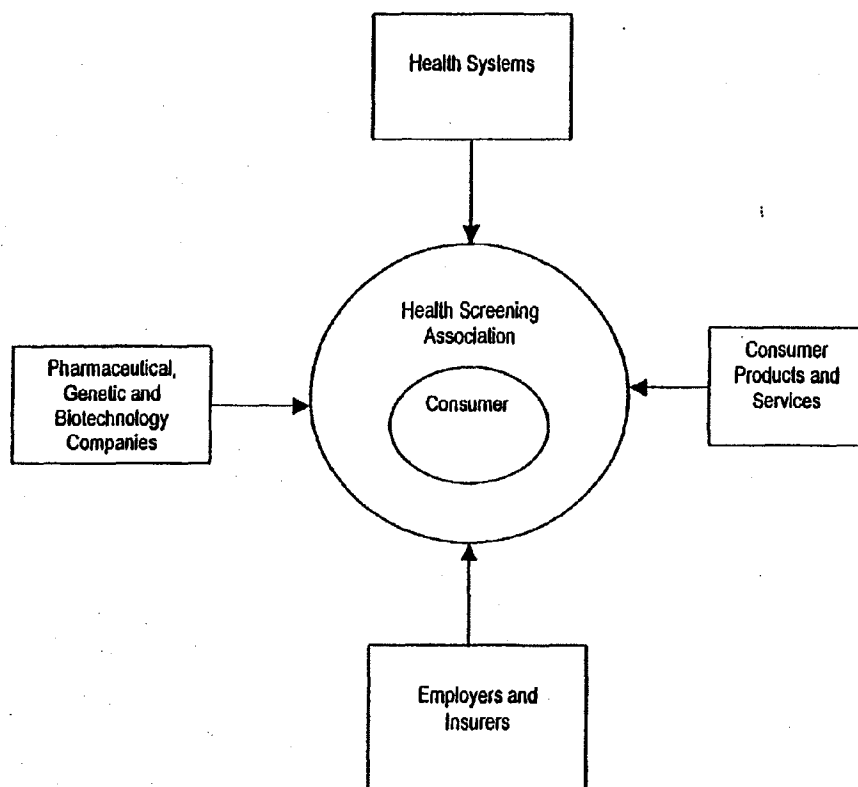


FIG. 1C

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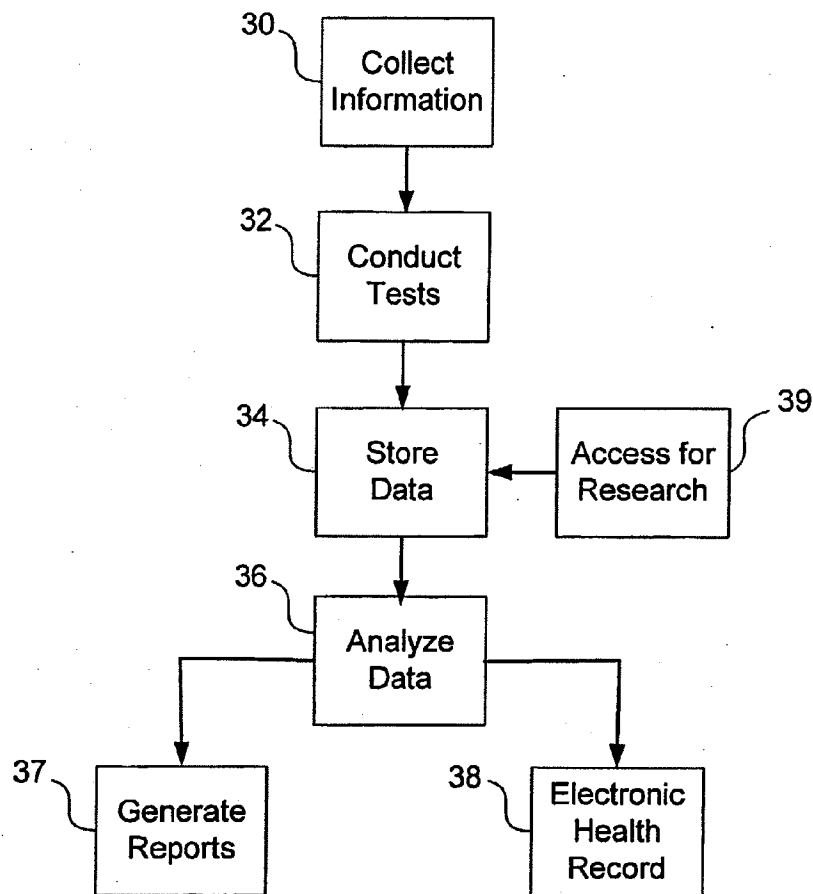


FIG. 2

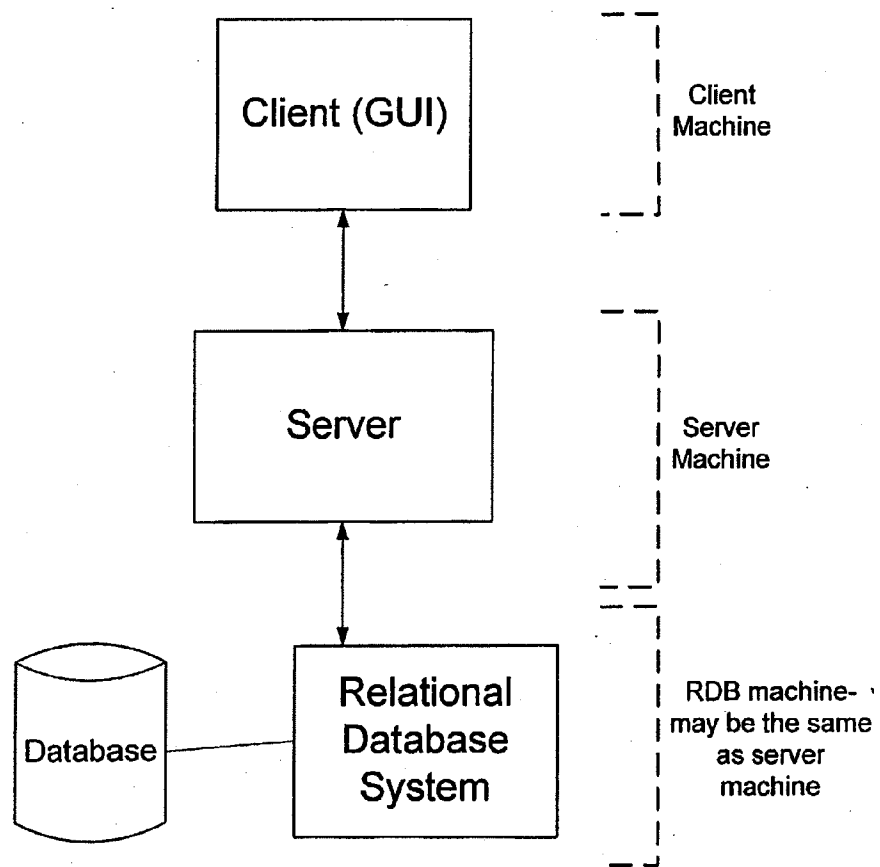


FIG. 3



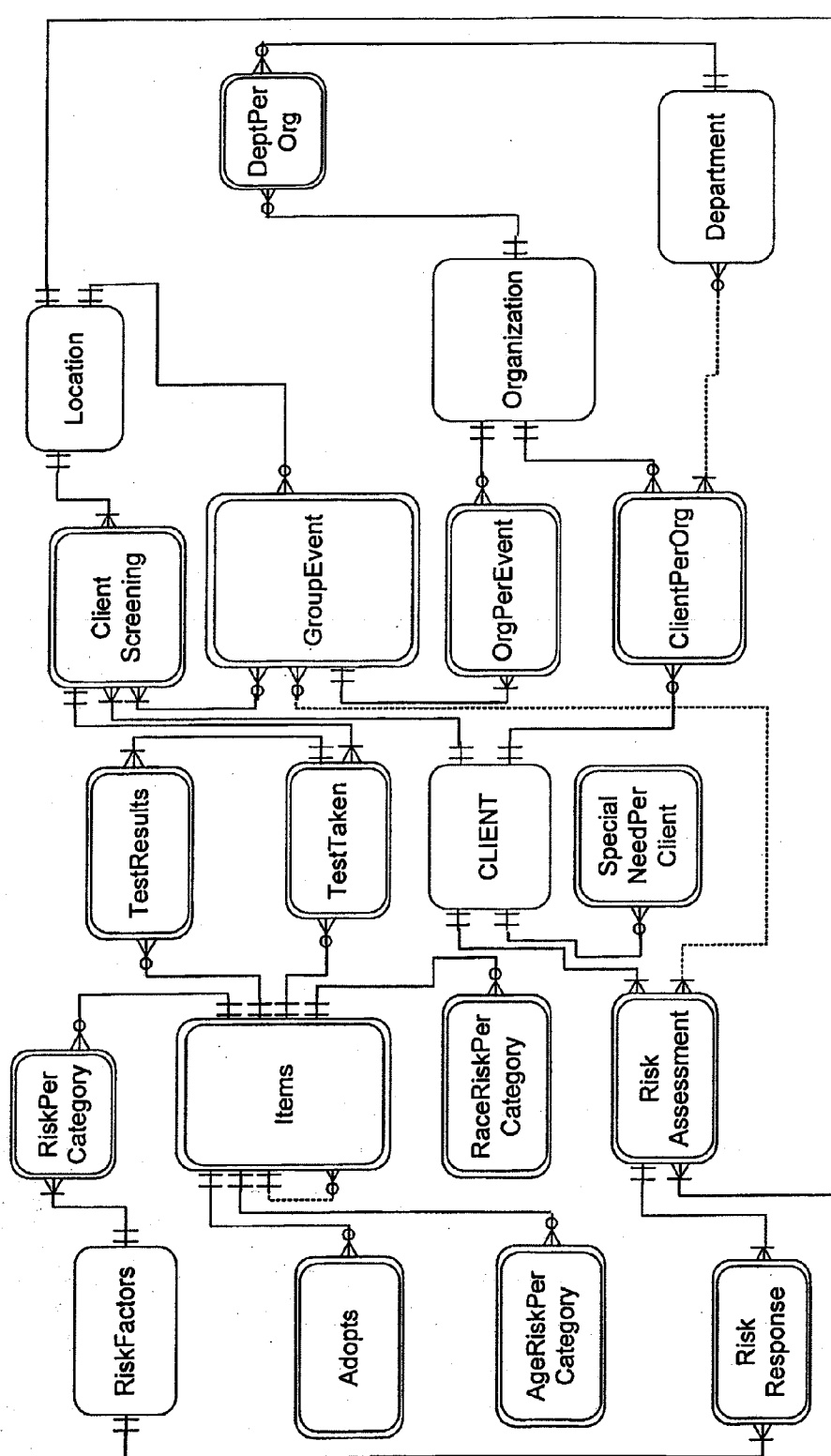


FIG. 4

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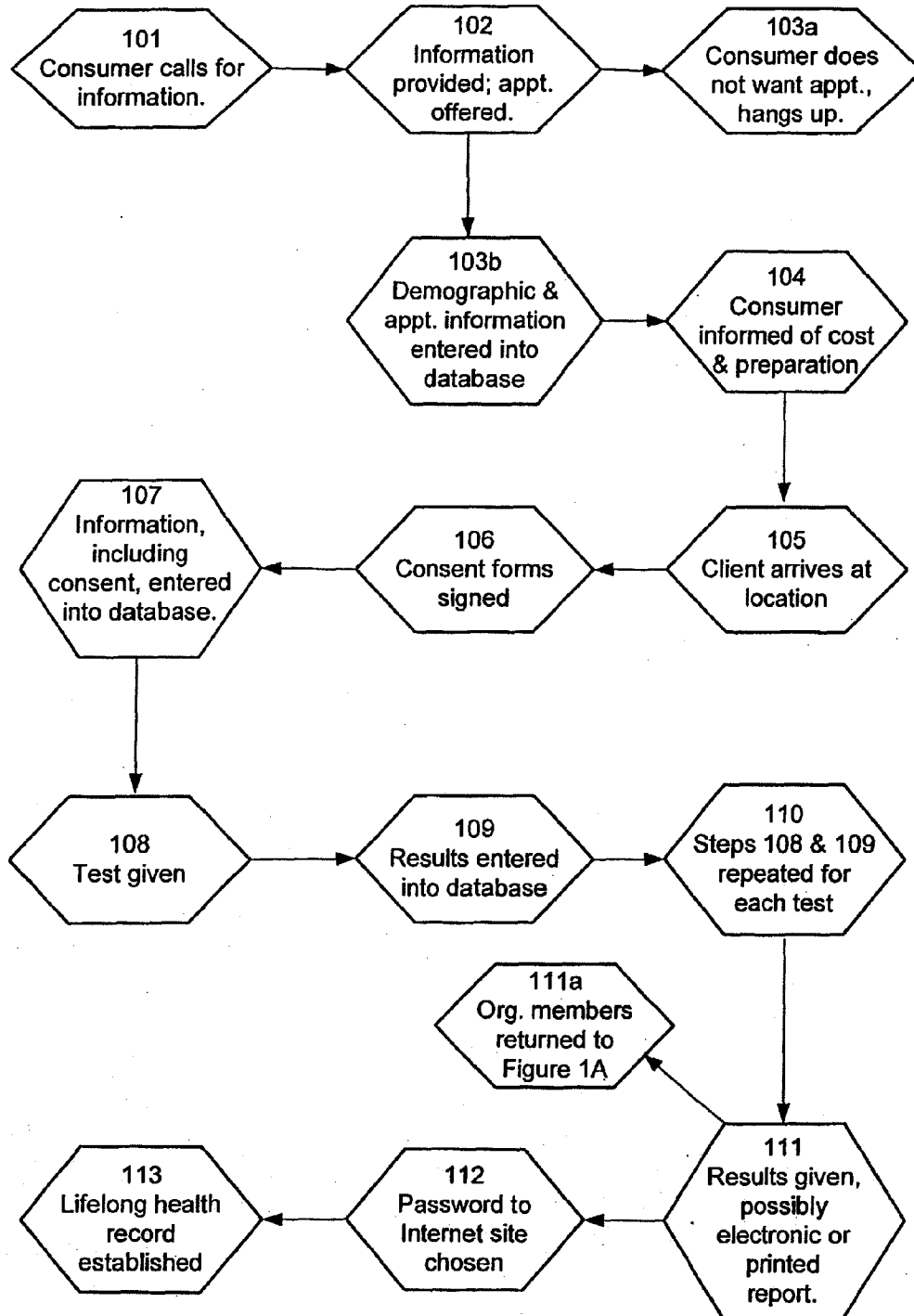


FIG. 5A

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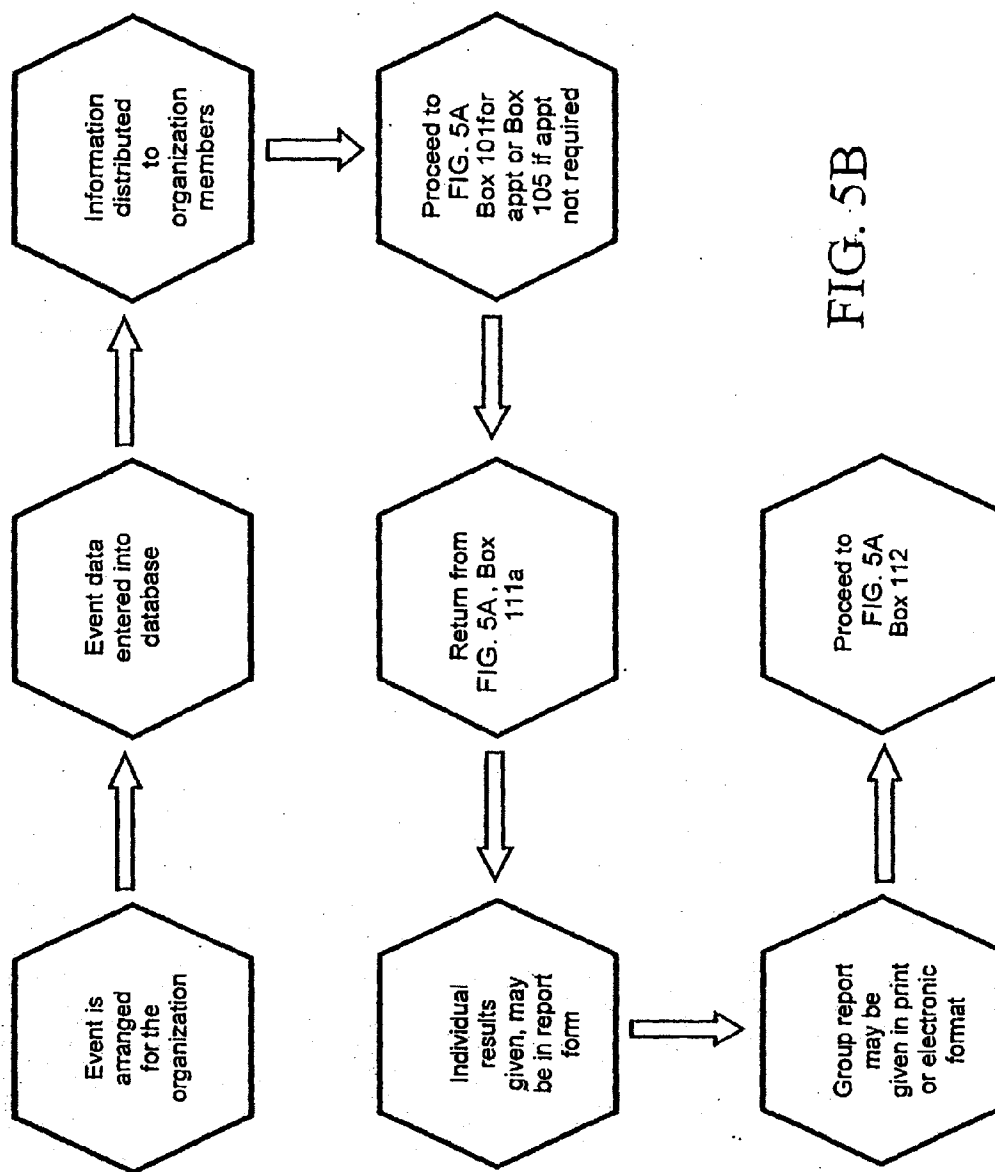


FIG. 5B

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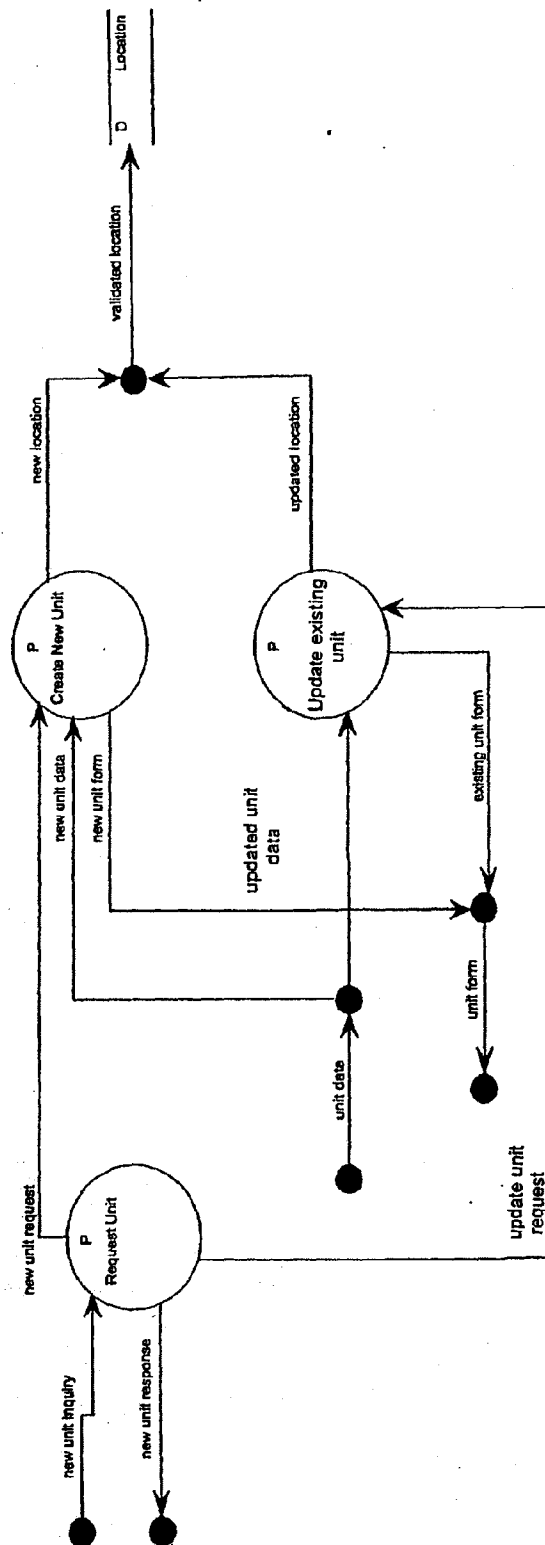


FIG. 6A

10/65

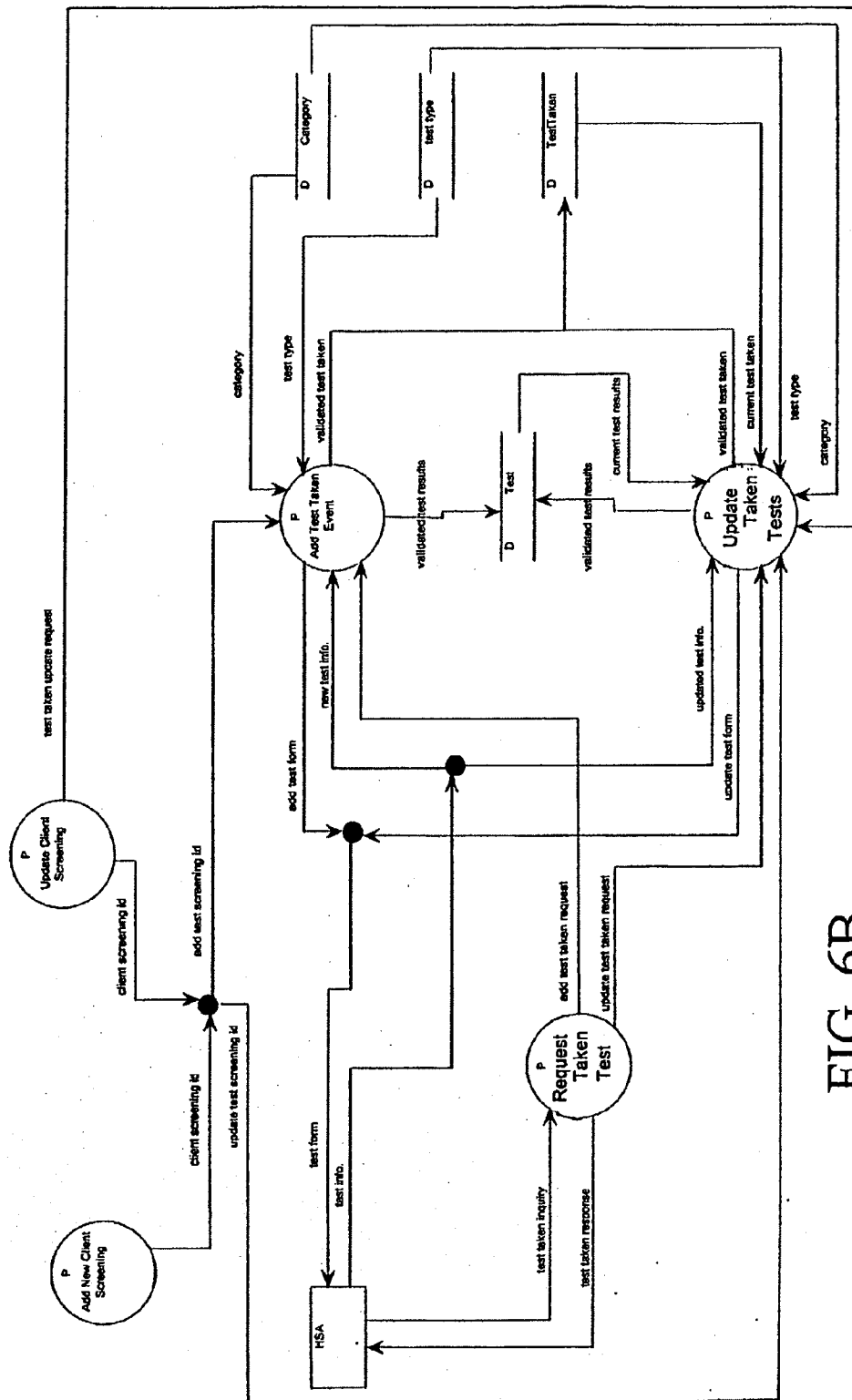


FIG. 6B

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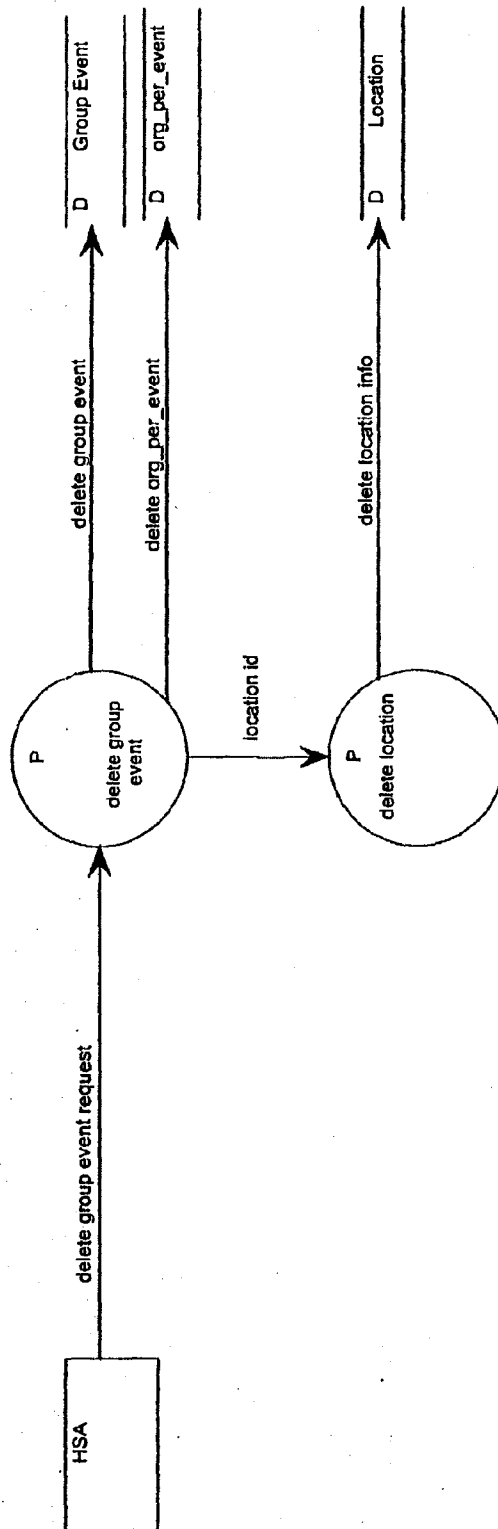


FIG. 6C

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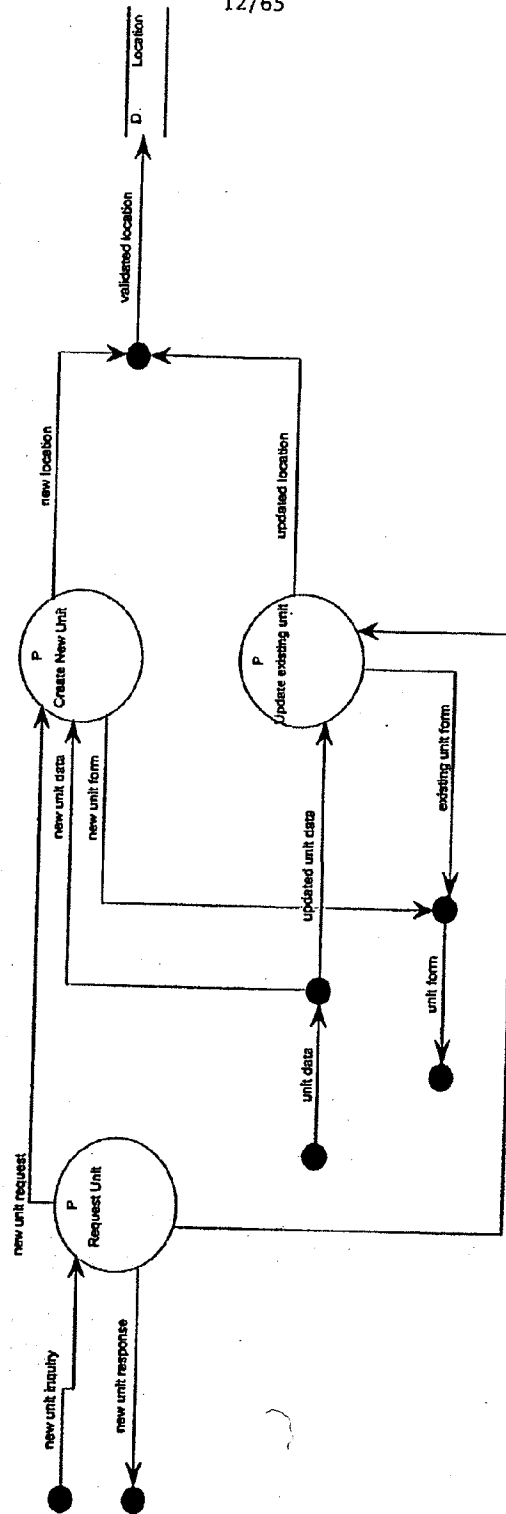


FIG. 6D

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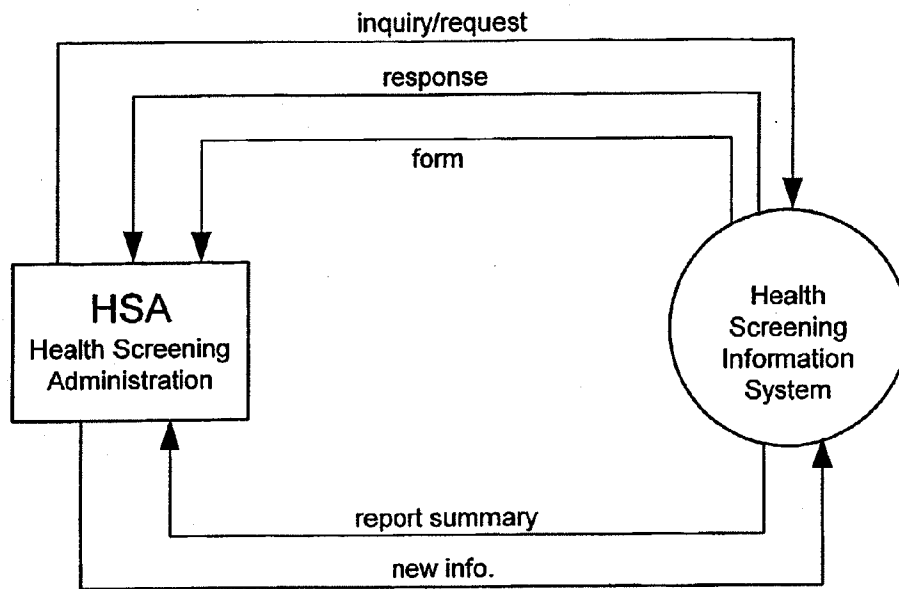


FIG. 6E



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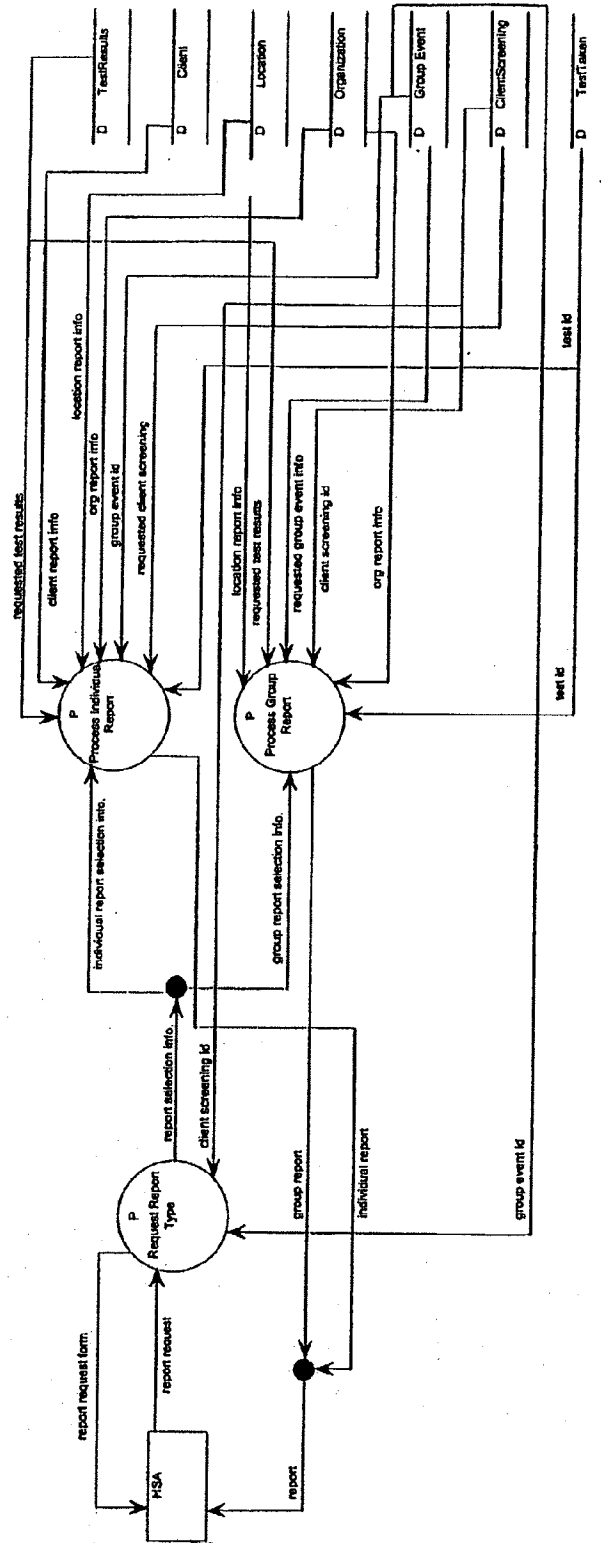


FIGURE 6F

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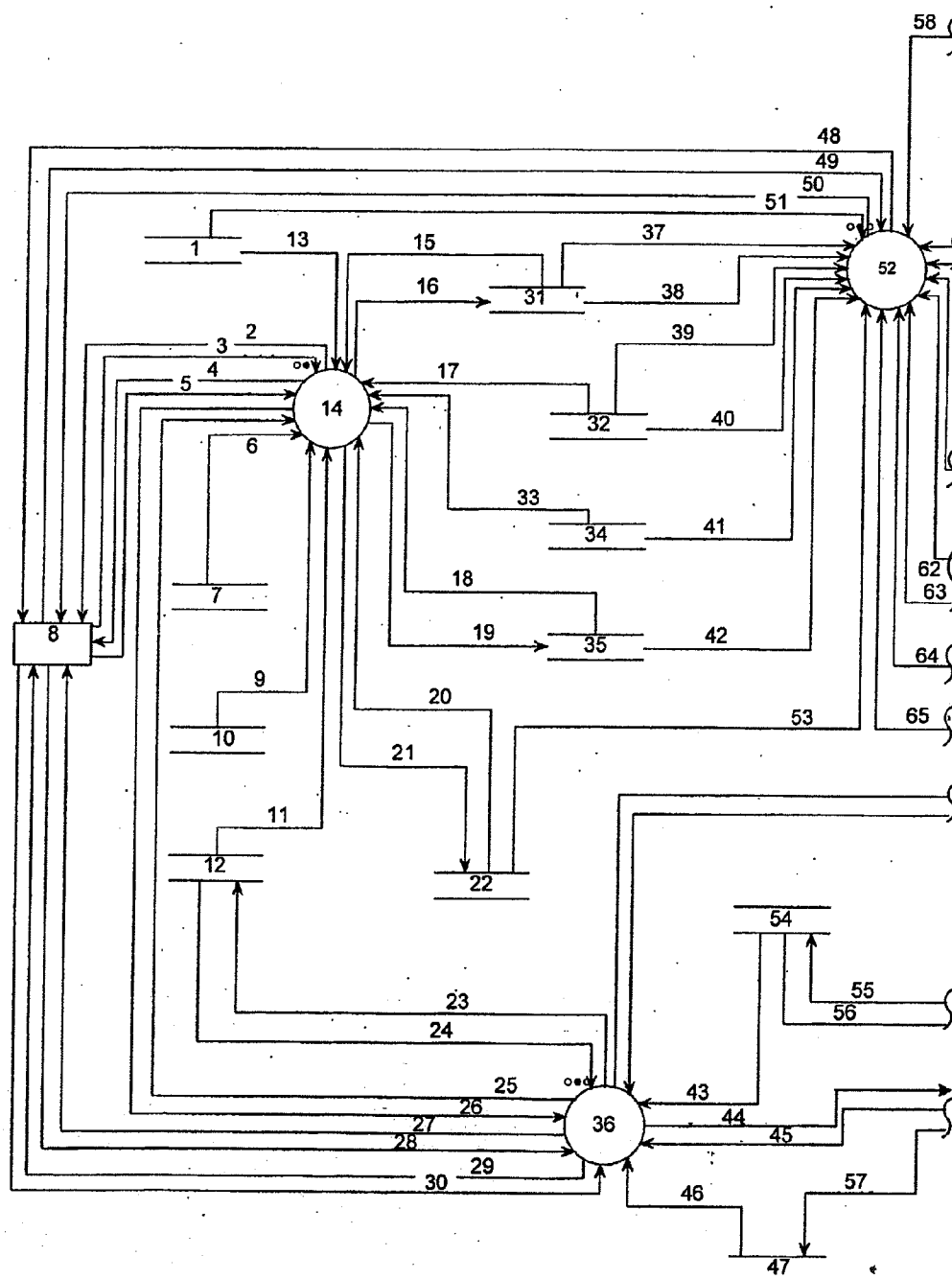


FIG. 6G-1

SUBSTITUTE SHEET (RULE 26)

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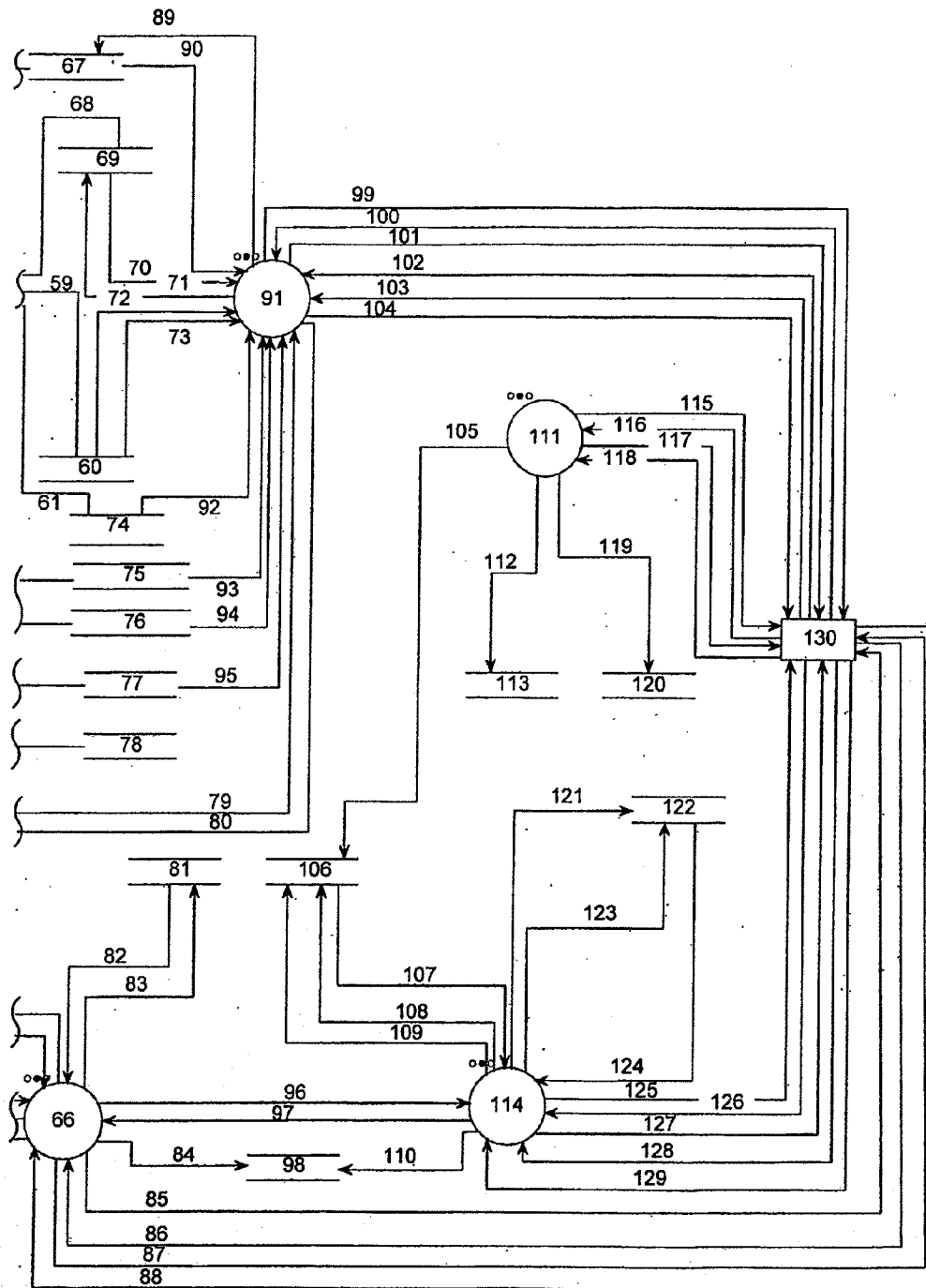


FIG. 6G-2

SUBSTITUTE SHEET (RULE 26)

**FIG. 6G-3****(Figure Legend)**

1= D Organization	39= group event id	85= organization form
2= screening form	40= requested group event info	86= organization inquiry
3= screening inquiry	41= location report info	87= organization response
4= screening response	42= test id	88= organization info
5= client screening info	43= Department info	89= validated risk response
6= test item info	44= Org demo change request	90= client risk response
7= D Items	45= organization id	91= P Process Client Risk Assessment
8= HSA	46= DeptPerOrg info	92= risk category
9= adopted item id	47= DeptPerOrg	93= age risk category
10= D Adopts	48= report request form	94= race risk category
11= screened client info	49= report request	95= client risk info
12= D Client	50= report	96= change group event req.
13= sponsoring organization	51= org report info	97= group event id
14= P Process Client Screening	52= P Generate Report	98= D org_per_event
15= current client screening info.	53= requested test results	99= risk assessment form
16= validated screening info.	54= D Department	100= risk assessment inquiry
17= associated group event	55= new dept info	101= risk assessment response
18= current test taken	56= current dept info	102= risk assessment info
19= validated test taken	57= DeptPerOrg Info.	103= risk assessment report request
20= current test results	58= client risk responses	104= risk assessment report
21= validated test results	59= risk factors	105= validated location
22= D TestResults	60= D Risk Factors	106= D Location
23= validated client info	61= risk category	107= current location info
24= current client info	62= age risk category	108= validated location info
25= request client screening	63= race risk category	109= delete location info
26= screening id	64= client report info	110= delete org_per_event
27= client demographic form	65= Department info	111= P Maintain HSA Data
28= client demographic inquiry	66= P Change Organization Demographic Information	112= validated test info
29= client demographic response	67= D RiskResponse	113= D Items
30= client demographic info	68= current risk assessment info	114= P Maintain Group Event
31= D ClientScreening	69= D RiskAssessment	115= maintain HSA data form
32= D GroupEvent	70= current risk assessment info	116= maintain HSA data inquiry
33= screening location	71= validated risk assessment info	117= maintain HSA data response
34= D Location	72= risk questions	118= new HSA data
35= D Test Taken	73= risk factors	119= adopt info
36= P Process Client Demographic Information	74= D RiskPerCategory	120= D Adopts
37= client screening id	75= D AgeRiskPerCategory	121= delete group event
38= requested client screening	76= D RaceRiskPerCategory	122= D Group Event
	77= D Client	123= validated group event
	78= D Department	124= current group event
	79= request client risk assessment	125= maintain group event form
	80= risk assessment id	126= maintain group event inquiry
	81= D Organization	127= maintain group event response
	82= current org info	128= group event info
	83= validated org info	129= delete group event request
	84= org_per_event info	130= HSA

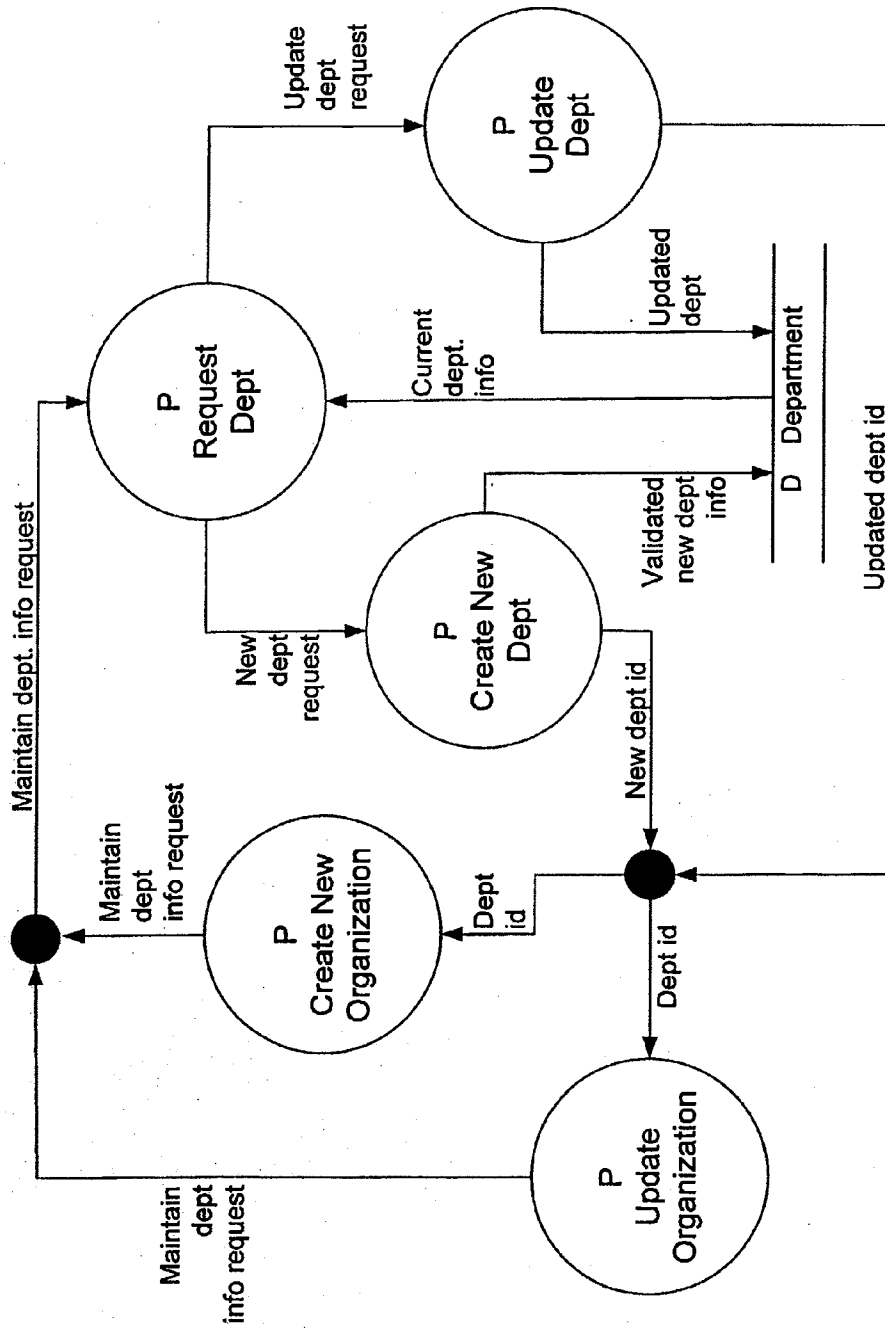


FIG. 6H

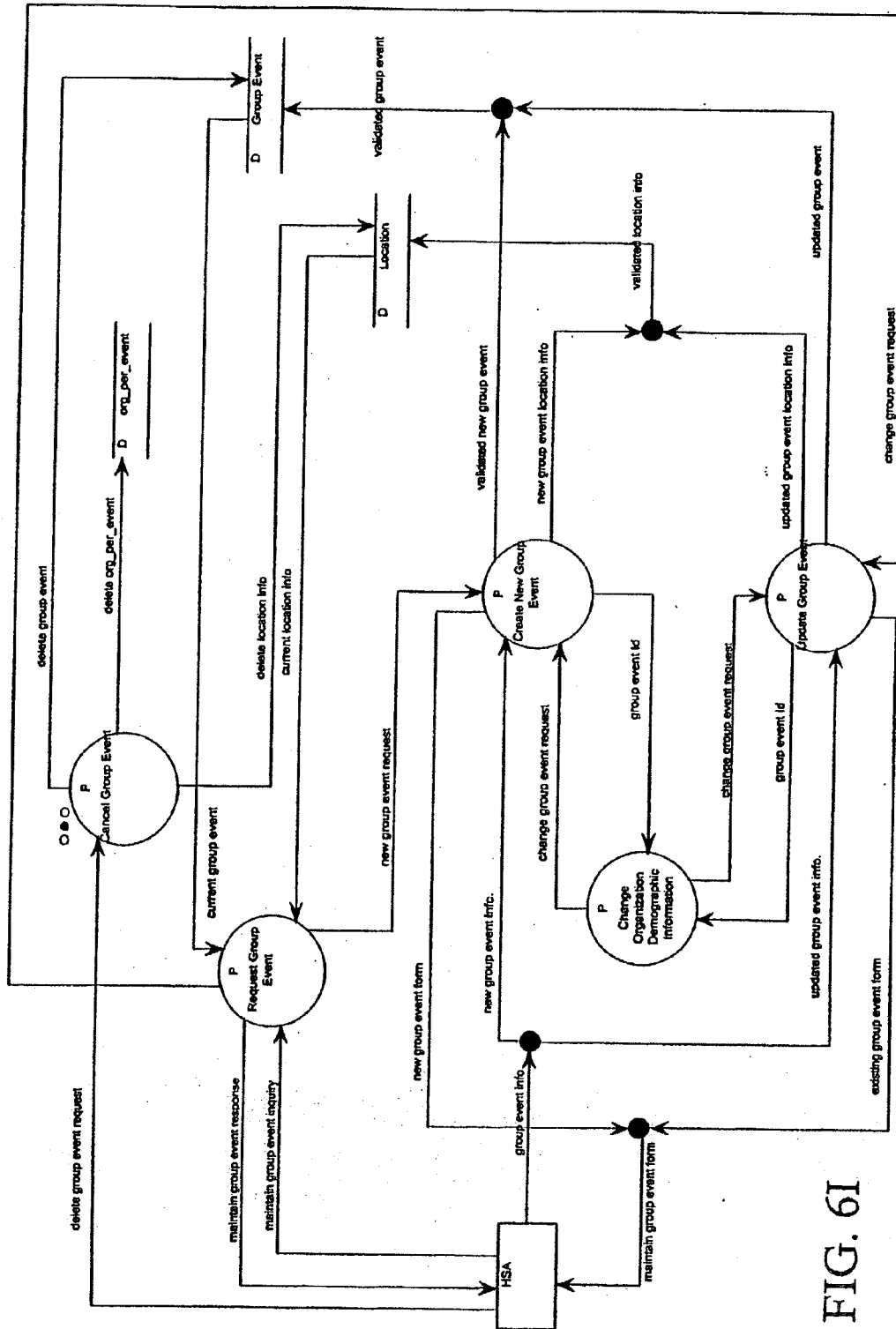


FIG. 6I

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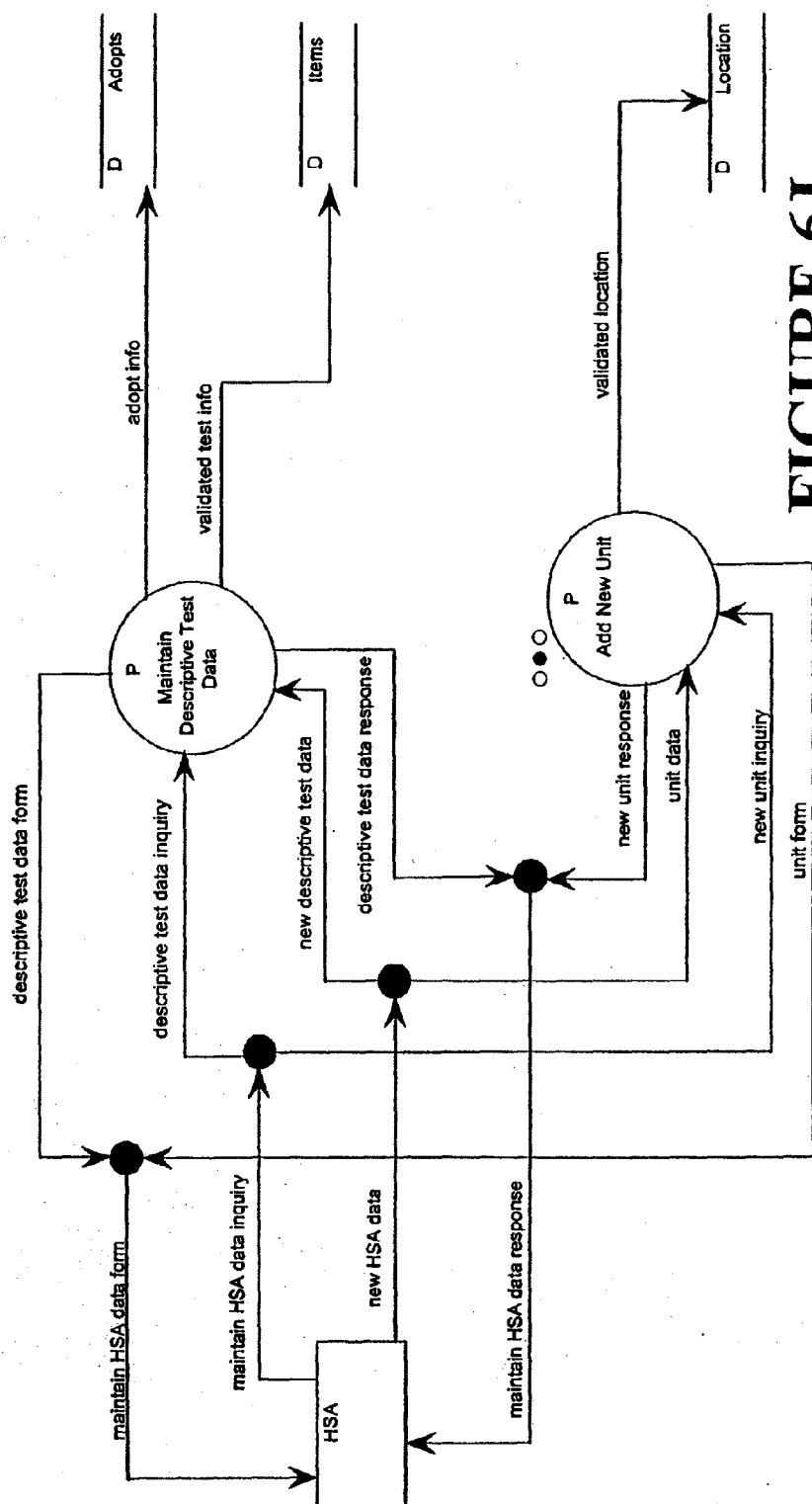
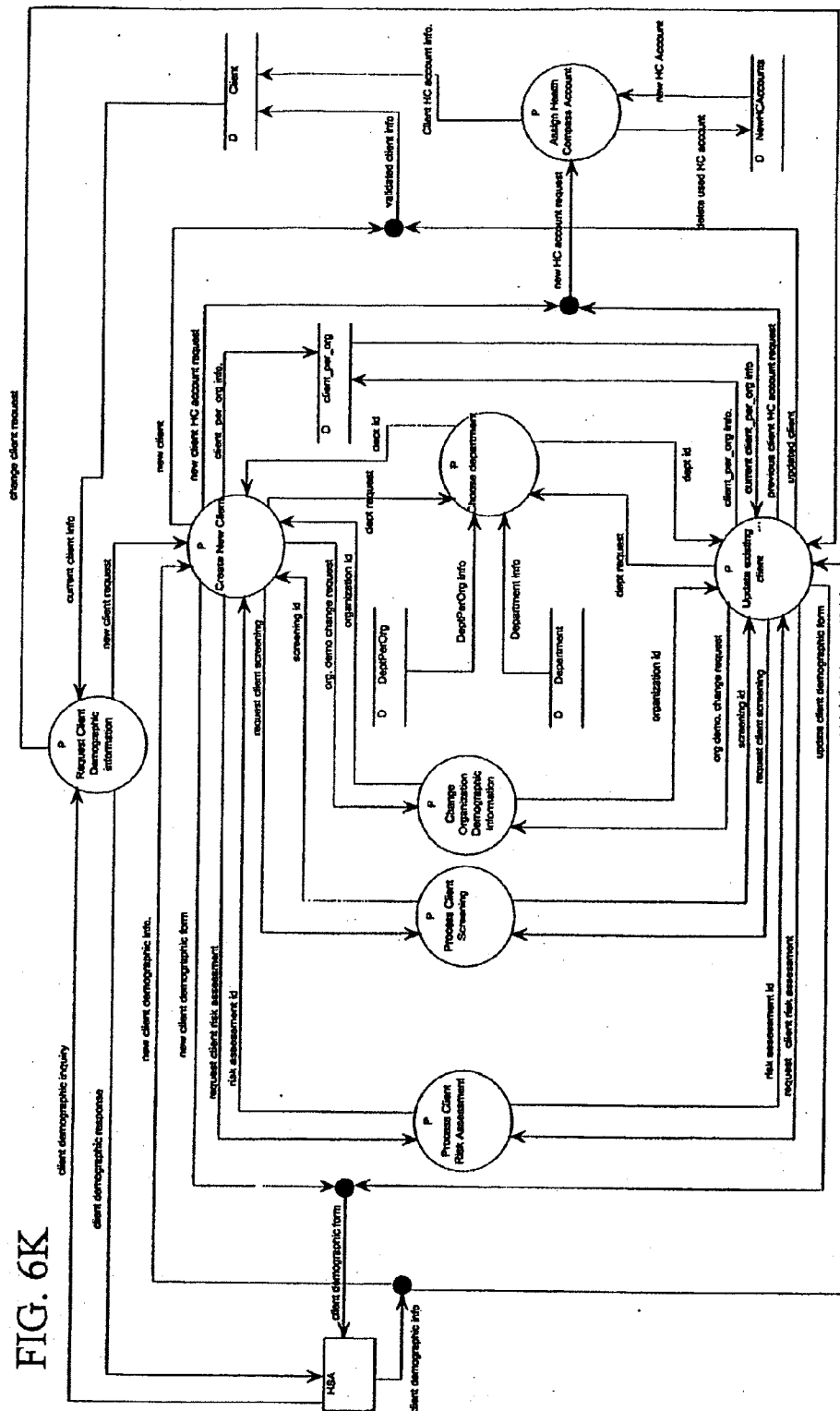
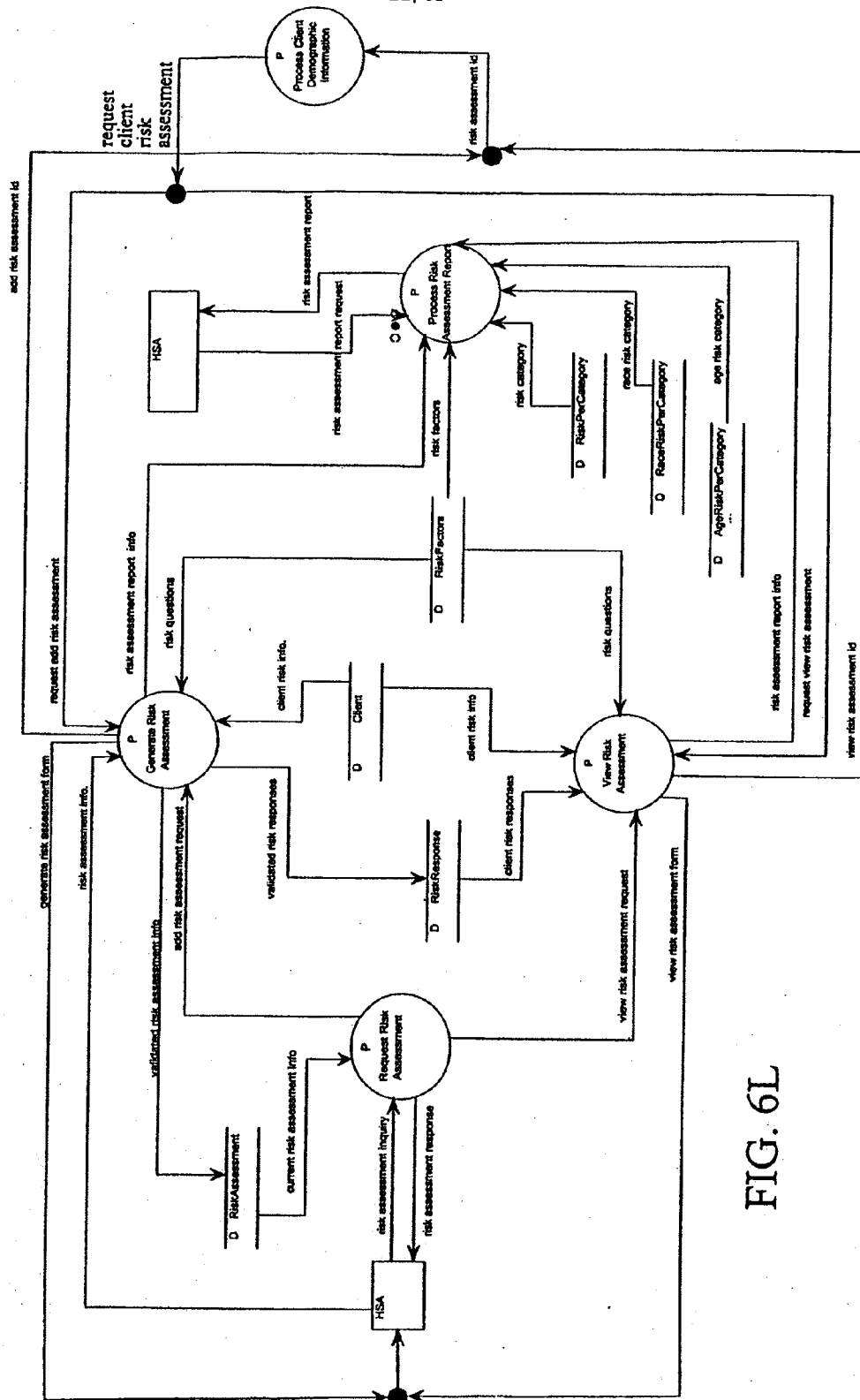
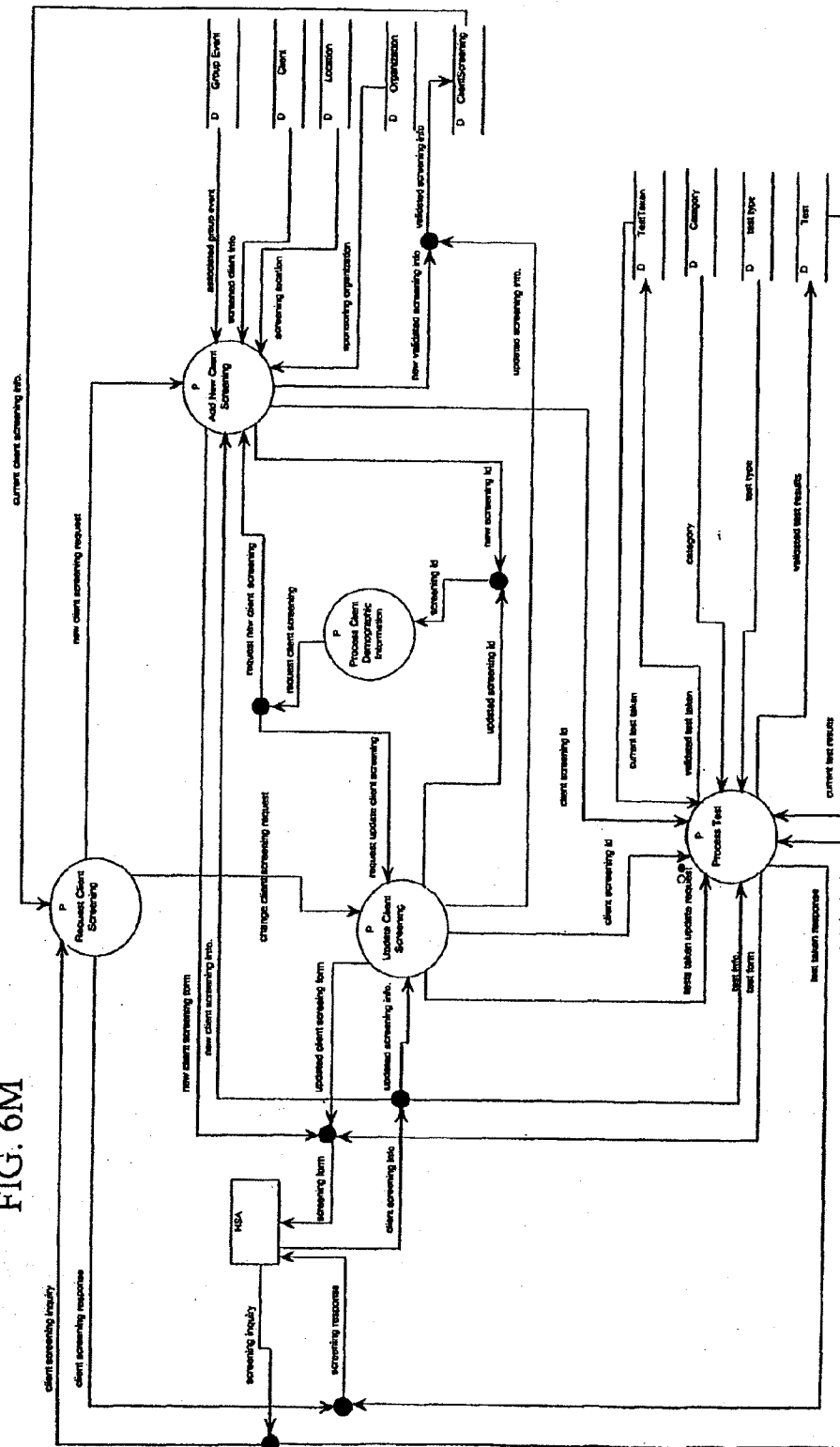


FIGURE 6J









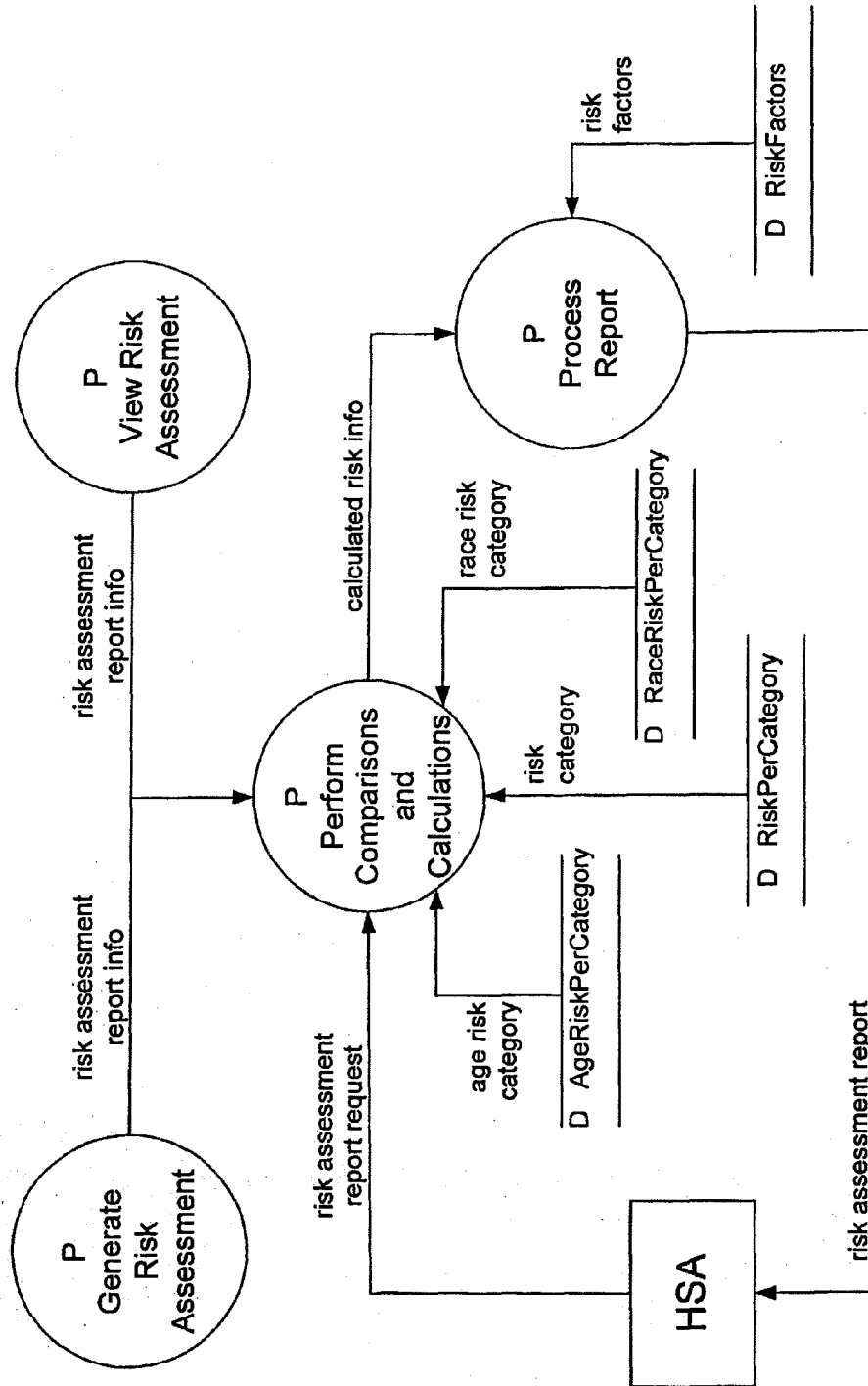


FIG. 6N

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## John Doe's Personal Health Record

### Information You Can Use

This record has been created especially for you by HealthScreen America to provide documentation of the results of your screening tests. The findings may help your physician identify health conditions and will help you monitor your health. By using this report along with other health information we provide, you can gain a greater understanding of your current health status and what you can do to preserve good health.

We also have established a confidential lifelong health record for you on our website, HealthScreenAmerica.com. There, you can maintain your screening results as well as add a wealth of other vitally important health information. Each time you visit HealthScreen America, your test results will be added to your Internet health record so you can track your long-term progress and compare results.

Research has shown you can dramatically increase the length and quality of life by identifying health conditions and seeking appropriate medical care early. Frequent tests to monitor these conditions, combined with educational information from our website and consultation with your personal physician, is recommended. As America's leading health-screening advocate, our mission is to help you live a longer, healthier life.

### See Your Physician

HealthScreen America is dedicated to helping you make thoughtful choices regarding your most precious possession: your health. The information presented in your report is in no way a substitute for a careful examination by a healthcare professional. You should always discuss specific health issues with your personal physician.

If you have any results that concern you or are abnormal, we strongly encourage you to see your doctor as soon as possible. Please be aware that no tests, including those conducted at the nation's top medical facilities, offer accurate results 100% percent of the time. Also, all test have limitations and can not detect all diseases present in the body. In many cases, your physician will want to conduct further testing. HealthScreen America recommends, in the strongest possible terms, that your healthcare regimen include periodic screenings in combination with regular consultation and examinations by your physician. We also encourage you to read and learn all you can.

### HealthScreen America's Credentials

HealthScreen America has a staff of highly skilled health care professionals supervised by a board-certified physician. Our screening tests use only the most sophisticated FDA-approved technology in conjunction with medically appropriate protocols selected by our advisory group of board-certified physicians. The protocols are based on information and recommendations from several professional medical organizations including the American Heart Association, American Diabetes Association, National Osteoporosis Association, Centers for Disease Control and Prevention, and U.S. Preventive Health.

### Your Records Are Confidential

HealthScreen America protects the privacy of each client. We will never sell, trade, rent, disclose or otherwise make available personally identifiable information about you to any third party without first receiving your permission. The only possible exceptions are 1) when we believe, in good faith, that the law requires disclosure or 2) to protect the rights or property of HealthScreen America.

FIG. 7A

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## SCREENING SUMMARY

## John Doe's Test Results

The following section contains a summary of your test results. It also provides information that explains what these results mean to help you make informed decisions about your personal wellness. We have provided a separate page of your test results for your personal physician to review. We encourage you to share this information with your doctor and learn as much as you can about your body, its processes and how to stay healthy.

TEST	YOUR RESULTS	NORMAL RANGE
<b>BODY COMPOSITION</b>		
Height:	71 in	
Weight:	185 lbs	
Body Mass Index:	25.8 kg/m <sup>2</sup>	Normal: 18.5 - 24.9 kg/m <sup>2</sup>
Total Body Fat:	18 %	Women: 19% - 26% Men: 12% - 18%
<b>CARDIOVASCULAR</b>		
Blood Pressure:	125/80 mm Hg	<130 / <85 mm Hg
Pulse (Heart Rate):	77 bpm	60 - 100 bpm
Total Cholesterol:	196 mg/dL	0 - 200 mg/dL
HDL:	45 mg/dL	35 - 150 mg/dL
Cholesterol/HDL Ratio:	3.0	1.0 - 4.5
LDL:	126 mg/dL	0 - 130 mg/dL
Triglycerides:	126 mg/dL	0 - 199 mg/dL
Arterial Elasticity: Pulse Pressure	45 pulse pressure	30-50
Ankle Brachial Index:		
Right Ankle	111 mm Hg	
Right Brachial	142 mm Hg	
Right ABI	1.28	Greater than 0.95
Left Ankle	109 mm Hg	
Left Brachial	130 mm Hg	
Left ABI	1.17	Greater than 0.95
Carotid Artery Scan:		
Right ICA Velocity:	45 cm / sec	< 110 cm/sec
Right CCA Velocity:	61 cm / sec	< 110 cm/sec
Right ICA/CCA Ratio:	0.74	< 1.8
Right Plaque Grade:	None/Minimal	None/Minimal
Left ICA Velocity:	46 cm / sec	< 110 cm/sec
Left CCA Velocity:	60 cm / sec	< 110 cm/sec
Left ICA/CCA Ratio:	0.77	< 1.8
Left Plaque Grade:	None/Minimal	None/Minimal
Comments:		
Abdominal Aortic Aneurysm:		
Aortic Diameter:	1.8 cm	Less than 3 cm
Aortic Plaque Grade:	None/Minimal	
Comments:		

FIG. 7B

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<b>DIABETES</b>		
Blood Glucose	93 mg/dL	Less than 126 mg/dL
<b>OSTEOPOROSIS</b>		
T-Score:	2.4 SD	greater than -1 SD compared your peak density
<b>LUNG CAPACITY</b>		
	3.24 FEV-1	75 %Predicted (nl >80%)
	4.10 FVC	77 %Predicted (nl >80%)
<b>THYROID SCAN</b>		
Comments:	Normal	Negative
<b>METABOLIC AND BIOCHEMICAL STUDIES (Blood Work)</b>		
NOTE: Results for metabolic and biochemical studies require analysis by an FDA-approved laboratory that is not on the HealthScreen America premises. Your results will be mailed in approximately five to seven days.		
<b>CT SCAN (available March, 2000)</b>		
Heart CAC Score:		CAC score of zero.
Lung CT Result:		Negative

**UNDERSTANDING YOUR RESULTS**

It is important to understand that no testing procedures, including those performed in physicians' offices and medical facilities, offer 100-percent diagnostic reliability. Our goal is to provide you with the highest-quality information to help you and your doctor make thoughtful decisions about your health. The screening results that HealthScreen America provides to you in no way substitute for a careful examination and regular medical care by a qualified healthcare professional.

In reading your test results, please keep in mind that a single test on its own offers minimal diagnostic value, but when combined with additional results it can significantly aid a physician's ability to diagnose important medical conditions. We encourage you to learn more about your test results and potential conditions by reading the following explanations as well as other information you gather. You also can ask for a consultation with our Registered Nurse Educator.

FIG. 7C

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Within healthy limits, your body's fat serves many useful functions. It helps insulate, protect and contour the body as well as provides a store of energy. But excess body fat can increase your risk for several diseases.

One hundred million Americans are overweight, putting their health at risk. The reasons for weight gain can include an inherited predisposition, poor dietary habits, a stressful environment, lack of exercise or even serious medical conditions.

#### YOUR RESULTS

Weight: 185 lbs  
 % Body Fat 18 %  
 Body Mass Index 25.8 kg/m<sup>2</sup>

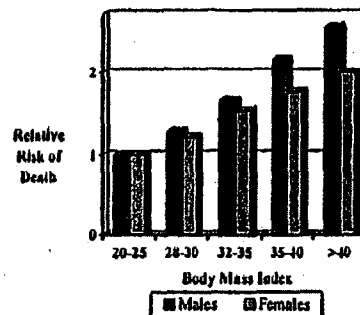
#### BODY FAT NORMAL RANGES

For Women: 19% - 26%  
 For Men: 12% - 18%

#### BODY MASS INDEX RISK

Normal: 18.5 - 24.9 kg/m<sup>2</sup>  
 Moderate: 25.0 - 29.9 kg/m<sup>2</sup>  
 High: 30.0 - 39.9 kg/m<sup>2</sup>  
 Very High: Over 40 kg/m<sup>2</sup>

Body Mass Index and Mortality



This graph shows that having a higher body mass index increases your relative risk of death. A relative risk of 1.0 means you are at normal risk for death. But a relative risk of 2.0 means that death is twice as likely to occur, and a relative risk of 3.0 means death is three times as likely. (Adapted from Body Mass Index and Mortality..., Calle et al., NEJM 1999; 341:15. American Cancer Society study of a million adults over a 14 year period.)

#### Body Metrics

The body mass index (BMI) is simply a measure of the ratio of your weight relative to your height. The portion of your body mass from fat also is reported along with the normal healthy range for body fat percentages. These measures can assist you and your physician in determining your optimal body composition.

#### Associated Health Risks

The American Cancer Society conducted a 14-year study of one million adults and found that being overweight (a body mass index of 25 or higher) is associated with an increased risk of death from cardiovascular disease as well as cancer.

#### Recommendation

If your test results indicate you are overweight, you should consider an effective weight loss program in consultation with your personal physician. Lifestyle modifications, including healthy eating patterns, nutritional education and regular exercise, usually form the foundation for lifelong weight management. If you received abnormal results on any of your body composition tests, we also suggest you consider the following tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Blood and Pulse Pressure, Carotid Artery Scan, Cholesterol, Diabetes, Lung Capacity and Homocysteine.

#### Testing Protocol

HealthScreen America uses the Body Comp Scale™ to determine your weight and body composition analyses. This device is FDA approved and accurate to within 2.5% of underwater weight testing. These tests were performed when you stepped onto a device similar to a weight scale.

FIG. 7D

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## CARDIOVASCULAR

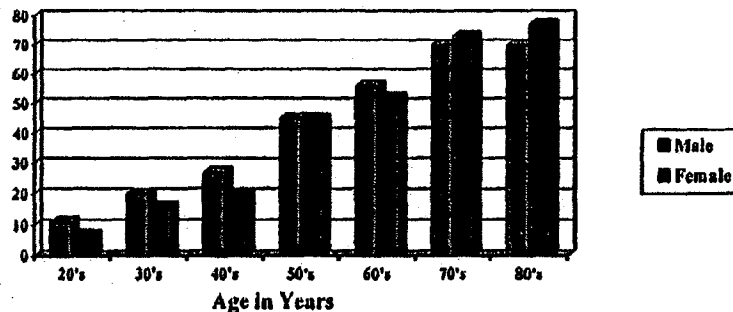
Cardiovascular disease is the leading cause of death for both men and women in the United States. The American Heart Association estimates that some form of this disease affects one in three Americans. HealthScreen America performs several screening tests to assist you and your physician in determining if you are at risk.

Early detection of risk factors aids in the timely diagnosis of disease and can prevent potentially disastrous complications. Cardiovascular risk factors include high blood pressure, elevated cholesterol, diabetes, smoking, obesity and a family history of heart disease.

HealthScreen America's cardiovascular screening tests help detect disease and prevent complications and can include:

Screening	Disease	Complication to be prevented
Blood Pressure	Hypertension	Stroke
Cholesterol	Heart Disease	Heart Attack
Arterial Brachial Index	Peripheral Vascular Disease	Amputation
Abdominal Aortic Aneurysm Scan	Aneurysm	Death

Cardiovascular Disease Incidence



The incidence of cardiovascular disease increases dramatically for both men and women as they age.

## CHOLESTEROL

The National Cholesterol Education Program recommends that all adults over 19 years of age should undergo serum cholesterol screening. An estimated 52 million American adults, could benefit from cholesterol lowering therapy. Unfortunately, many individuals have not been screened and do not know their cholesterol levels. HealthScreen America can help.

FIG. 7E



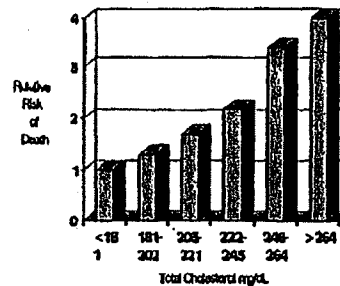
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**CHOLESTEROL** continued**Your Results**

Total Cholesterol (TC): 196 mg/dL  
 HDL (Good Cholesterol): 45 mg/dL  
 Cholesterol/HDL Ratio: 3.0  
 LDL (Bad Cholesterol): 126 mg/dL

**Normal Range**

Total Cholesterol (TC): 0 - 200 mg/dL  
 HDL (Good Cholesterol): 35 - 50 mg/dL  
 Cholesterol/HDL Ratio: 1.0 - 4.5  
 LDL (Bad Cholesterol): 0 - 130 mg/dL

**Cholesterol Level and Risk of Cardiovascular Death**

This graph shows that the relative risk of death increases with higher cholesterol levels. A relative risk of 1.0 indicates a normal risk for death. A relative risk of 2.0 means that death is twice as likely to occur, and so forth. (Adapted from Multiple Risk Factor Intervention Trial data for 361,662 men over six years. *Lancet*, 10/86.)

**Associated Health Risks**

Cholesterol is a fat-like substance (lipid) found in our cells, our food and our blood. When cholesterol levels are elevated, the cholesterol can be deposited and accumulate within the walls of arterial blood vessels. This gradually leads to vascular injury, plaque formation, inflammation and the blockage of normal blood flow. The "bad" cholesterol or LDL promotes this process, while the "good" cholesterol, HDL, can remove lipid buildup from your blood vessels. Knowing your entire lipid profile is essential to understanding your risk.

**Recommendations**

As the accompanying graph shows, a desirable level of total cholesterol is generally less than 200 mg/dL. The good cholesterol, HDL, should be greater than 35 mg/dL; the higher the better. The total cholesterol/HDL ratio is a useful means of quickly determining cardiovascular risk. A desirable ratio is 4.5 or lower.

It is important to know that if you have other cardiovascular risk factors, you should try to maintain your LDL at less than 130 mg/dL. Those with known coronary heart disease will want their LDL less than 100 mg/dL or even lower, if recommended by their physicians. Your situation is unique, and you should review and discuss your results with your physician. In general, guidelines for controlling your cholesterol include:

1. Know your cholesterol profile and track it regularly;
2. Maintain a healthy body weight;
3. Practice good nutrition, such as a diet high in fiber, low in cholesterol and low in saturated fat;
4. Consider an exercise program after consulting your physician.

If any of your cholesterol tests are abnormal, we also suggest you consider the following HealthScreen America screening tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Blood and Pulse Pressure, Body Composition, Carotid Artery Scan and Homocysteine.

**Testing Protocol**

HealthScreen America utilizes the Cholestech LDX system to obtain your lipid profile. A simple finger prick blood sample is all that is required. The Cholestech system is FDA-approved and proven to achieve accuracy that was previously attainable only from clinical laboratories.

FIG. 7F

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**TRIGLYCERIDES**

Triglycerides are a form of fat that is found in the body and in the food we eat.

**Your Results**  
126 mg/dL

Normal Ranges	
Desirable	0 - 199 mg/dL
Moderate:	200 - 399 mg/dL
High:	400 - 999 mg/dL
Very high:	More than 1000 mg/dL

**Associated Health Risks**

Elevated triglycerides are often closely associated with obesity and diabetes. Other causes of elevated triglyceride levels include inherited conditions that can lead to premature cardiovascular death as well as disorders of the thyroid, kidneys or liver.

**Recommendations**

If your test results fall outside the normal range, we encourage you to notify your physician. Maintaining a healthy body weight, reducing saturated fat and cholesterol in your diet, and regular exercise are often recommended to those with high triglyceride levels.

If your triglyceride levels are abnormal, we suggest you also consider taking the following tests: Cholesterol, Metabolic Studies, Abdominal Aortic Aneurysm, Ankle Brachial, Blood and Pulse Pressure, Body Composition, Carotid Artery Scan and Homocysteine.

**Testing Protocol**

We evaluated your triglyceride level from a sample of your blood, using sophisticated, FDA-approved measurement technology.

**ARTERIAL STUDIES**

Your arteries form a tree that distributes blood, with vital oxygen and nutrients, throughout the body. Abnormalities of this system can be the source of complications such as stroke, non-healing ulcers, numb or cold extremities, painful leg cramps and even amputation or sudden death.

HealthScreen America provides several screening procedures to determine the health of your arterial system. These include:

1. Blood Pressure
2. Pulse Pressure
3. Ankle Brachial Index
4. Carotid Artery Scan
5. Abdominal Aortic Aneurysm Screen

**BLOOD PRESSURE**

High blood pressure (hypertension) is one of the most important modifiable risk factors for cardiovascular disease. It affects 43 million American men and women. Sadly, about a third of these individuals are unaware they have the problem. Even when high blood pressure is correctly diagnosed, it is often under treated and poorly controlled. The Health Statistics National Health and Nutrition Survey III found that more than 70 percent of those with hypertension did not have the condition under adequate control.

**FIG. 7G**

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**BLOOD PRESSURE**

Your results are expressed as a ratio, for example 120/80 mm Hg. The first number is the systolic reading and indicates the pressure in the brachial artery (upper arm) is 120 mm Hg during the pumping phase of the heart. The second number is the diastolic and it means that when the heart is between beats, the blood pressure is 80 mm Hg. HealthScreen America measured your blood pressure by using a pressure cuff that was placed around your upper arm and connected to an advanced, FDA-approved cardiovascular-evaluation device. The blood pressure criteria of the Joint National Committee of Detection, Evaluation and Treatment of High Blood Pressure (JNC-VI) presented below help you interpret your results.

**Your Results**  
 BP Systolic (top #): 125 mmHg  
 BP Diastolic (bottom #): 80 mmHg

Normal Ranges	Systolic (top#)	Diastolic (bottom#)	
Normal	less than 130	less than 85	
High Normal	130-139	85-89	
Hypertension			
Moderate	(stage 1)	140-159	90-99
High	(stage 2)	160-179	100-109
Very High	(stage 3)	180-209	110-119
Critical	(stage 4)	more than 210	more than 120

**Associated Health Risks**

Hypertension often is a silent killer, causing no symptoms. If untreated, it can lead to complications such as heart attack, stroke, congestive heart failure, kidney failure and peripheral vascular disease.

**Recommendation**

Because each individual's blood pressure can vary, several readings should be taken for an accurate evaluation. If your blood pressure falls outside the normal range, we suggest you consult a physician to determine whether follow-up action is needed. Your physician may prescribe medications or a special diet to help control your blood pressure.

If your blood pressure is high, we also recommend considering the following tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Body Composition, Carotid Artery, Cholesterol and Diabetes.

**PULSE PRESSURE**

Arteriosclerosis is a medical term indicating a literal "hardening" of the arteries. This process occurs as a result of age as well as several disease processes. Fortunately, modern technology has given us a non-invasive way to evaluate the stiffness of your arterial system, providing you with a warning of possible problems ahead.

**Your Results** 45      **Normal Range of Pulse Pressure**

30 to 50

**Associated Health Risks**

Decreased arterial elasticity or decreases in the flexibility of an artery may indicate hardening or arteriosclerosis from cardiovascular disease. One of the best indicators of this process is the pulse pressure. Elevations of pulse pressure have been shown to predict cardiovascular disease and death.

**Recommendations**

If your test results indicate an elevation of your pulse pressure, you should review them with your physician. If your results are abnormal, we also recommend taking the following HealthScreen America tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Body Composition, Carotid Artery Scan, Cholesterol and Homocysteine.

FIG. 7H

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**PULSE PRESSURE continued****Testing Protocol**

HealthScreen America uses a FDA approved device for this test. The simple, painless test uses a pressure cuff placed on your upper arm. Your pulse pressure is determined by subtracting the diastolic measurement (the lower value) from the systolic reading (the upper value). As arterial health and elasticity decrease, the pulse pressure will increase.

**ANKLE BRACHIAL INDEX**

The Ankle Brachial Index (ABI), test is a useful screening test for peripheral vascular disease, which results in a lack of proper circulation.

**Your Results**

	Ankle	Brachial	Ratio
Right	111mm Hg	142mm Hg	1.28
Left	109mm Hg	130mm Hg	1.17

Ranges	ABI
Normal	> 0.95
Mild obstruction:	0.71 - 0.95
Moderate obstruction:	0.31 - 0.70
Severe obstruction:	0.00 - 0.30

**Associated Health Risks**

This test is useful in determining your risk for peripheral vascular disease, a narrowing or blockage of the arteries that carry blood to your arms and legs. This condition can lead to cool, numb or painful hands and feet, non-healing ulcers or even amputation.

**Recommendations**

If your Arterial Brachial Index is lower than 0.96 it may be related to obstruction in your arteries and peripheral vascular disease. You should bring the results to the attention of your physician, who can determine your need for further evaluation and treatment.

We suggest you also consider taking the following tests: Abdominal Aortic Aneurysm, Arterial Elasticity, Body Composition, Carotid Artery Scan, Cholesterol and Homocysteine.

**Testing Protocol**

The FDA-approved Unelix ABI device was used to evaluate your ABI. Pressure cuffs were placed on your arms and legs to measure blood flow. This system applies computerized Doppler technology to determine test results rapidly.

**CAROTID ARTERY SCAN**

This screening test evaluates the condition of your carotid arteries, the main arteries supplying blood to the brain and face.

**Your Results**

	Right	Left
ICA velocity:	45cm / sec	46cm / sec
CCA velocity:	61cm / sec	60cm / sec
ICA/CCA ratio:	0.74	0.77
Plaque grade:	None/Minimal Critical	None/Minimal

Velocity	Degree of Blockage:	Risk:
<110cm/sec	0 - 40%	Low- Mod
>120cm/sec	41 - 59%	High
>130cm/sec	60% to 79%	Very High
	>250cm/sec	Greater than 80%

**Associated Health Risks**

When arteriosclerosis and cholesterol plaques affect the carotid arteries, a build-up or release of debris in the artery can suddenly block blood flow and cause a disabling or fatal stroke in the brain.

FIG. 7I

**CAROTID ARTERY SCAN continued****Recommendations**

It is important to note this test is not designed to produce diagnostic results, but to detect possible problems. The carotid scan determines the how fast the blood is flowing within your common carotid artery (CCA) and your internal carotid artery (ICA). These arteries supply the majority of blood to the brain and face. By detecting abnormal velocities the carotid scan can determine if there is evidence of blockage present within the artery.

If your results are abnormal, you should consult with your physician for further evaluation immediately. The ICA to CCA ratio is also reported and should be less than 1.8. If abnormal, your physician should seek further testing. The degree of blockage present in the carotid arteries will help guide your physician in your treatment and whether there is any need for surgical intervention. Be sure to review your results with your physician.

As part of your overall assessment for heart attack and stroke, you should also consider taking the following tests: Abdominal Aortic Aneurysm, Ankle Brachial Index, Blood and Pulse Pressure, Body Composition, Cholesterol and Homocysteine.

**Testing Protocol**

The (Siemens and/or GE) ultrasound scanner wand is applied to the side of the neck with gentle pressure. This FDA-approved device uses high-frequency sound waves that bounce off the carotid artery. It creates actual images of the arteries and can "look inside" to determine the presence of blockage.

**ABDOMINAL AORTIC ANEURYSM SCAN**

The aorta is the largest blood vessel in the body. It is the main channel for blood leaving the heart and circulating to the rest of the body. Throughout your lifetime, it is subjected to the blood flow and pressure of each and every heartbeat.

**Your Results**

Aortic Diameter: 1.8cm

**Normal Range**

Less than 3 cm

3 to 5 cm

More than 5 cm

Within normal limits

Aneurysm requiring evaluation

High risk for rupture, seek medical attention immediately

**Associated Health Risks**

Over time, the walls of the aorta can weaken and expand. This process is known as aortic aneurysm formation. There are an estimated 1.5 million adults with this condition but only a fraction will be aware of the risk they face. Ruptures of aortic aneurysms are responsible for the sudden deaths of approximately 15,000 Americans each year.

**Recommendations**

If your Abdominal Aortic Scan shows an aortic diameter of 3 cm or more, you should review these results with your personal physician. Often it is necessary to follow an aortic aneurysm closely to ensure it is not enlarging over time and at risk for sudden rupture.

We also suggest you consider the following HealthScreen America tests: Ankle Brachial Index, Body Composition, Carotid Artery Scan, Cholesterol and Homocysteine.

**Testing Protocol**

A FDA-approved (Siemens and/or GE) scanner uses ultrasound waves to form images of the aorta, determining the aortic diameter. A small ultrasound wand was gently passed over the abdominal area.

**FIG. 7J**

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**DIABETES**

There are two types of diabetes: Type I is caused by the complete lack of insulin production, while Type II is caused by insufficient or ineffective insulin. Type I diabetes often occurs in childhood while Type II diabetes, also known as "adult onset" diabetes, is closely linked to obesity. Being overweight can lead to "insulin resistance". Insulin is a hormone produced by the pancreas that is important in carbohydrate, protein and fat metabolism. Often those with early stage diabetes have no obvious symptoms, but warning signs are listed below.

**Warning Signs of Diabetes**

1. Frequent urination
2. Excessive thirst
3. Dry mouth
4. Blurred vision
5. Poor wound healing
6. Recurrent infections
7. Numbness or tingling
8. Erectile dysfunction (impotence)

**Your Results**

Glucose level: 93mg/dL

**Normal Range**

Normal is less than 126 mg/dL

Consult your physician if greater than 126mg/dL

**Associated Health Risks**

Diabetes is a major cause of blindness, kidney failure, amputation, heart attack and stroke. It affects more than 16 million Americans. Yet millions of individuals have never been screened, diagnosed or received needed therapy. Although there is currently no cure for the disease, it can be controlled with proper treatment. Control of diabetes can reduce the frequency and severity of associated retinal, kidney and nerve damage by 50 - 70%.

The Centers for Disease Control and Prevention (CDC) recommends that all those age 25 and older receive screening for diabetes. It estimates the average delay in the diagnosis of diabetes is 9 to 12 years from the onset of disease. Early detection can prevent years of damage to vital organs and permanent injury to your health.

**Recommendations**

If your FDA-approved fasting blood glucose is higher than 126 mg/dL, we suggest you consult your physician as soon as possible. Only a doctor can make a definitive diagnosis and determine the proper course of treatment, if needed.

If your results are abnormal, we also suggest you consider taking the Body Composition Test and Cardiovascular screening at HealthScreen America, including Blood Pressure, Cholesterol, Homocysteine, Carotid Artery Scan and Ankle Brachial Index.

**Testing Protocol**

We perform a fasting plasma glucose test using a small sample of blood obtained from an easy finger-prick.

FIG. 7K

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## OSTEOPOROSIS

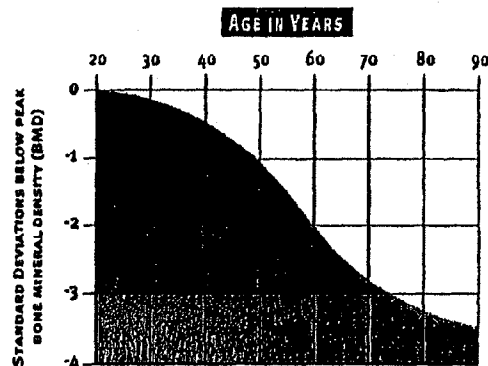
Americans are living longer than ever before, and as our population ages, osteoporosis is emerging as a major health issue. Peak bone density is reached in early adulthood (usually by age thirty), then over time the bones of your skeleton become progressively more fragile. This loss of bone density leaves one especially susceptible to fractures. Unfortunately, osteoporosis is often discovered late in the disease process. Early screening is critical to the recognition, prevention and effective treatment of osteoporosis. While the disease can occur in men, women are at higher risk and should begin screening in their 20s.

The T-Score shown here compares your bone density to that of young, healthy adults. It is usually a negative value and compares your bones to when you were young and your bones were at their strongest. The lower the T-Score the lower your bone density and more fragile your bones. Your physician will take into account many factors (such as your history, age and other risk factors) to diagnose and recommend treatment for osteoporosis.

### Your Results

2.4 SD T-Score

<b>Normal Range</b>		
Greater than	-1.0	SD
<b>Osteoporosis results in:</b>		
1.	Tooth loss	
2.	Fractures of the vertebrae	
3.	Back deformity	
4.	Loss of mobility	
5.	Chronic pain	
6.	Depression and low self esteem	
7.	Loss of independence	
8.	Hip fractures and death	



### Health Risks

Osteoporosis is a silent epidemic affecting 28 million American women. Half of women over the age of fifty are destined to develop osteoporosis in their lifetime. Few of these women understand that the risk of death from osteoporosis is as great as the risk of death they face from breast cancer. Osteoporosis can lead to hip fracture and life-threatening complications.

### Recommendations

If your results are outside the normal range, we strongly suggest that you bring this to the attention of your physician. A T-Score between -1.0 and -2.5, indicates your bone density is low, this is known as osteopenia. Low bone density is of concern since the bones tend to weaken over time. Thus osteopenia can be the first evidence of your risk for osteoporosis. A T-Score lower than -2.5 is regarded as osteoporosis by the World Health Organization.

You should also be aware of the risk factors for osteoporosis:

1. Caucasian, Hispanic, or Asian decent
2. Slender or small body build
3. Early menopause or postmenopausal state
4. Inadequate calcium in diet

FIG. 7L

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**OSTEOPOROSIS** continued

5. Lack of regular weight bearing exercise
6. High intake of caffeine or alcohol
7. Smoking
8. A family history of osteoporosis
9. Diseases such as asthma and rheumatoid arthritis

To reduce your risk, you should consider:

1. A diet or supplements with 1,200 to 1,500mg of daily calcium
2. Vitamin D 400 to 800 IU daily

**Testing Protocol**

This screening test is performed by placing your heel into the Lunar ultrasonometer, a FDA-approved device, which uses ultrasound technology to evaluate the density of your bones.

FIG. 7M

**LUNG CAPACITY**

This test evaluates the condition of your lungs and their ability to expand and release air normally. It is beneficial in detecting airflow abnormalities from a variety of causes. The FVC (forced vital capacity) score tells how much air your lungs can hold. The FEV-1 (forced expiratory volume) score tells how much air you can blow out of your lungs within one second.

The number provided in the Percent Predicted column compares your lung capacity to the expected normal range. Your FVC and FEV-1 scores should be 80 percent or more of that predicted.

Your Results	Percent Predicted
3.24 FEV-1	75 %
4.10 FVC	77 %

**Associated Health Risks**

The Lung Capacity screening test can help detect lung diseases such as emphysema or chronic obstructive pulmonary disease that is often associated with smoking. It also can provide evidence of asthma or reactive airway disease. Asthma often goes undetected despite being the fifth leading cause of death in the United States.

**Recommendation**

If your Lung Capacity results are not in the normal range, we encourage you to see your doctor. Two of the best things you can do to maintain good lung health are to exercise regularly and avoid smoking.

**Testing Protocol**

The test is performed by exhaling into an FDA-approved Simplicity NPB-500 spirometer.

FIG. 7N



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**THYROID SCAN**

This screening test detects abnormalities in the thyroid such as cysts, tumors, goiter (an enlargement of the thyroid gland) and nodules. The test often finds "non-palpable" nodules, which cannot be felt in a physical exam and can only be detected through medical imaging. Thyroid nodules are common, occurring in about one-third of all people, according to the American Cancer Society. The vast majority of these growths are not cancerous and pose no risk to your health.

**Your Results**      **Normal**

Normal
Abnormal

**Comments****Associated Health Risks**

When abnormalities are found in the thyroid, there is a possibility of a risk of thyroid cancer, and hyperthyroidism (too much thyroid hormone) or hypothyroidism (too little thyroid hormone).

Individuals at greatest risk for thyroid cancer are those with a history of exposure to radiation or a family history of thyroid cancer. Solitary thyroid nodules greater than 1.0 cm in size and those with suspicious features on a thyroid ultrasound or a thyroid nuclear scan are of the greatest concern and may require a biopsy or excision.

**Recommendations**

If thyroid abnormalities are detected, you should consult your physician for further evaluation. Multiple small nodules can develop when a thyroid goiter is present because of an underlying thyroid hormone imbalance. A metabolic screening of thyroid hormone levels is usually performed. Your personal physician will help you decide which tests are better in your situation.

As part of your overall assessment for the thyroid gland, you should also consider taking a simple blood test at HealthScreen America to determine your thyroid profile. The blood test measures the thyroxine level (T4) from the thyroid gland and a thyroid stimulating hormone level (TSH) from the pituitary gland.

**Testing Protocol**

An ultrasound scanner wand is applied to the neck with gentle pressure. This FDA-approved ultrasound device (either Siemens or General Electric) uses high-frequency sound waves that bounce off the thyroid. It creates actual images of the thyroid gland and can "look inside" to search for abnormalities.

**FIG. 70**

## METABOLIC AND BIOCHEMICAL STUDIES

Several of the tests offered by HealthScreen America are sophisticated blood studies that require processing by an outside laboratory. These include:

- Tumor-marker tests such as CEA, CA-125 and PSA help identify cancer at an early stage
- Hormone studies such as the TSH, T4, FSH, testosterone and estrogen levels, hormone deficiencies or imbalances
- Hematologic studies that can uncover anemia or other problems involving your red cells, white cells and platelets
- Biochemical studies evaluate the health of vital organs such as the kidneys, liver, gallbladder and pancreas; also, electrolyte and chemical abnormalities can point to underlying disease
- Screening factors such as homocysteine levels are known to be associated with an increased risk of disease

These complex metabolic analyses do not lend themselves to simple discussion and explanation. Every test HealthScreen America performs is reported along with an expected normal range. The highest standards are used in these laboratory analyses. Nevertheless, no tests can always be 100-percent reliable.

**Your Results** Results require analysis of your blood sample by a national laboratory. Results will be mailed to you in five to seven days.

### Normal Ranges

CA 125: 0 - 35 IU/mL

CEA: Smokers: 0 - 5.0 ng/mL

Non-Smokers: 0 - 3.0 ng/mL

PSA: 0 - 4 ng/mL

Blood Count:

WBC: 4.0 - 10.5  $10^3$ /uL

RBC: 4.10 - 5.60  $10^6$ /uL

Hgb: 12.5 - 17.0 g/dL

Hct: 36.0 - 50.0%

MCV: 80 - 98 fL

MCH: 27.0 - 34.0 pg

MCHC: 32 - 36 g/dL

Neutrophils: 40 - 74%

Lymphocytes: 14 - 46%

Monocytes: 4 - 13%

Eosinophils: 0 - 7%

Basophils: 0 - 3%

Abslt Cnt: Neutrophil: 1.8 - 7.8  $10^3$ /uL

Abslt Cnt: Lymphocyte: 1.0 - 4.8  $10^3$ /uL

Abslt Cnt: Monocyte: 0 - 0.8  $10^3$ /uL

Abslt Cnt: Eosinophil: 0 - 0.4  $10^3$ /uL

Abslt Cnt: Basophil: 0 - 0.2  $10^3$ /uL

Platelets: 140 - 415  $10^3$ /uL

Complex Metabolic Panel:

Glucose, Plasma: Fasting: 65 - 109 mg/dL

Glucose: 65 - 109 mg/dL

BUN (Blood Urea Nitrogen): 9 - 27 mg/dL

Creatinine: 0.5 - 1.5 mg/dL

BUN/Creat Ratio: 6 - 25

Uric Acid: Male Range 3.5 - 9.0 mg/dL

Uric Acid: Female Range 2.2 - 7.7 mg/dL

Sodium: 135 - 148 mmol/L

Potassium: 3.5 - 5.5 mmol/L

Chloride: 96 - 109 mmol/L

Carbon Dioxide: 20 - 32 mmol/L

Calcium: 8.5 - 10.6 mg/dL

Ionized Calcium: 3.5 - 5.2 mg/dL

Inorganic Phosphorus: 2.5 - 4.5 mg/dL

Total Protein: 6.0 - 8.5 g/dL

Albumin: 3.5 - 5.5 g/dL

Globulin: 2.2 - 4.1 g/dL

Albumin/Globulin Ratio: 0.9 - 2.0

Total Bilirubin: 0.1 - 1.2 mg/dL

Alkaline Phosphatase: 25 - 160 U/L

GGTP (Gamma-Glutamyl Transferase): 0 - 85 U/L

LDH (Lactic Dehydrogenase): 0 - 240 U/L

SGOT (Serum Glutamic Oxaloacetic Transaminase):  
0 - 45 U/L

SGPT (Serum Glutamic-Pyruvic Transaminase):  
0 - 50 U/L

Serum Iron: 40 - 180 ug/dL

FSH: Pre-menopausal: 2.5 - 10.2 mIU/mL

Post-menopausal: 23.0 - 116.3 mIU/mL

Homocysteine: Normal: 5 - 15 umol/L

Optimal: Less than 10 umol/L

Thyroid Panel:

TSH (thyroid stimulating hormone): 0.4 - 5.5 mIU/L

Uptake (thyroid hormone uptake): 24 - 39%

T4 (thyroxine): 4.5 - 12.0 ug/dL

T7 (free thyroxine index): 1.4 - 4.9 U

FIG. 7P

**METABOLIC AND BIOCHEMICAL STUDIES** *continued***Recommendations**

These tests will assist your physician in better understanding your current health status. It is helpful to monitor and track changes over time, so periodic screening is recommended. Any abnormal results should be brought promptly to your physician's attention and reviewed in detail.

**FIG. 7Q**

### **Consider A Program Of Regular Screenings**

While all medical specialists and organizations promote basic screening tests as a critical component of good preventive care, many differ about when and how often tests should be performed. Some organizations make recommendations based on the benefits of a test weighed against how much payers will have to pay for them.

You may prefer to be more assertive about your health. We recommend that you be screened annually to detect problems earlier and to have a point of reference in case you receive abnormal results in the future.

If you alter your diet, medication, exercise or lifestyle habits, or have medical complications, you may want to be checked more often to chart your progress. HealthScreen America is always ready to help you remain well informed about your health.

### **If This Is Ever A Concern**

If you have any questions or concerns about our tests your medical status, or wellness issues, we encourage you to speak with our Registered Nurse Educator.

If you are dissatisfied in any way or have any type of problem, we want to hear from you. Please write or call the Center Manager or our Client Advocate Director at 421-7777. You have our promise we will do everything possible to ensure you are happy with your HealthScreen America experience.

*\*\* Let us know if you would like information about our mobile screening units, available for screening events at your workplace, churches, community and civic organizations.*

FIG. 7R

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### Your Lifelong Health Record On The Web

When you underwent your screening tests, you elected to keep a record of your results in the Lifelong Health Record on our website, [healthscreenamerica.com](http://healthscreenamerica.com). Here is the information you need to access your secure, confidential Lifelong Health Record:

Your Account Number:  
Your Registration Code:

Your screening test results have been posted in your own private file on our website and are ready for your use immediately. Just access [www.healthscreenamerica.com](http://www.healthscreenamerica.com). It's absolutely FREE.

HealthScreen America's Lifelong Health Record is much more than a place to safely and confidentially keep records of your screening tests. It is a comprehensive record of your health history. If you choose, this information can be available to others such as healthcare professionals in an emergency or family members who can help you. You can keep track of things such as:

- Medications you are taking or have taken in the past-and which ones worked best
- Your family's medical history
- Records of all your doctor and hospital visits
- Historical data like your blood pressure and cholesterol levels
- Allergies and reactions you've had
- Immunizations you've received
- Emergency medical information and contacts
- Your healthcare providers
- Where you got your prescriptions filled
- Which hospital you prefer
- Insurance information
- When you experienced certain symptoms
- And any other information you believe is important to your health

In addition, you can use the HealthScreen America website to:

- Look up in-depth medical information, from arthritis to wheezing
- Learn about your health risks through questionnaires
- Automatically receive important health reports
- Use interactive tools for enhancing your health

We encourage you to make frequent use of the wealth of information available to you at [healthscreenamerica.com](http://healthscreenamerica.com). It could be the most valuable health tool you've ever used-and it won't cost you a penny.

FIG. 7S

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**PHYSICIAN'S REPORT****HealthScreen America Test Results For John Doe**

This page contains a summary of screening tests completed for your patient by HealthScreen America. Tests were performed using state-of-the-art, FDA-approved technology operated by highly skilled health technologists, supervised by a board-certified physician.

At HealthScreen America, we strongly encourage each screening test participant to consider our services as part of an overall program of good health, to be undertaken in close cooperation and consultation with their personal physician.

If you would like more information regarding the testing protocols, testing technology or results, we encourage you to call HealthScreen America at 904-346-440. We welcome the opportunity to speak with you.

TEST	RESULTS	NORMAL RANGE
<b>BODY COMPOSITION</b>		
Height:	71	
Weight:	185 lbs	
Body Mass Index:	25.8 kg/m <sup>2</sup>	Normal: 18.5 - 24.9 kg/m <sup>2</sup>
Total Body Fat:	18 %	Women: 19% - 26% Men: 12% - 18%
<b>CARDIOVASCULAR</b>		
Blood Pressure:	125 / 80 mm Hg	<130 / <85 mm Hg
Pulse (Heart Rate):	77 bpm	60 - 100 bpm
Total Cholesterol:	196 mg/dL	0 - 200 mg/dL
HDL:	45 mg/dL	35 - 150 mg/dL
Cholesterol/HDL Ratio:	3.0	1.0 - 4.5
LDL:	126 mg/dL	0 - 130 mg/dL
Triglycerides:	126 mg/dL	0 - 199 mg/dL
Arterial Elasticity:	45 pulse pressure	30-50
Ankle Brachial Index:		
Right Ankle	111 mm Hg	
Right Brachial	142 mm Hg	
Right ABI	1.28	Greater than 0.95
Left Ankle	109 mm Hg	
Left Brachial	130 mm Hg	
Left ABI	1.17	Greater than 0.95
Carotid Artery Scan:		
Right ICA Velocity:	45 cm / sec	< 110 cm/sec
Right CCA Velocity:	61 cm / sec	< 110 cm/sec
Right ICA/CCA Ratio:	0.74	< 1.8
Right Plaque Grade:	None/Minimal	None/Minimal
Left ICA Velocity:	46 cm / sec	< 110 cm/sec
Left CCA Velocity:	60 cm / sec	< 110 cm/sec
Left ICA/CCA Ratio:	0.77	< 1.8
Left Plaque Grade:	None/Minimal	None/Minimal

**FIG. 7T**

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TEST	RESULTS	NORMAL RANGE
Abdominal Aortic Aneurysm: Aortic Diameter: Comment:	1.8 cm	Less than 3 cm
<b>DIABETES</b> Blood Glucose	93 mg/dL	Less than 126 mg/dL
<b>OSTEOPOROSIS</b> T-Score	2.4 SD	Greater than -1.0 SD
<b>LUNG CAPACITY</b> FEV-1 FEV-1 %Predicted	3.24 75	Greater than 80% of predicted result
FVC FVC % Predicted	4.10 77	Greater than 80% of predicted result
<b>THYROID SCAN</b> Comments:	Normal	Negative

**Note:**

1. Metabolic and Biochemical studies are performed at a national reference laboratory and will be available within 7 days of visit.
2. CT results for cardiac calcification scores await review by a cardiologist and lung cancer screening will receive a radiologist's interpretation. These reports will be available under separate cover.

FIG. 7U

**John Doe's Personal Health Record*****METABOLIC AND BIOCHEMICAL STUDIES***

Several of the tests offered by HealthScreen America are sophisticated blood studies that require processing by an outside laboratory. These include:

- Tumor-marker tests such as CEA, CA-125 and PSA help identify cancer at an early stage
- Hormone studies such as the TSH, T4, FSH, testosterone and estrogen levels, hormone deficiencies or imbalances
- Hematologic studies that can uncover anemia or other problems involving your red cells, white cells and platelets
- Biochemical studies evaluate the health of vital organs such as the kidneys, liver, gallbladder and pancreas; also, electrolyte and chemical abnormalities can point to underlying disease
- Screening factors such as homocysteine levels are known to be associated with an increased risk of disease

These complex metabolic analyses do not lend themselves to simple discussion and explanation. Every test HealthScreen America performs is reported along with an expected normal range. The highest standards are used in these laboratory analyses. Nevertheless, no test can always be 100-percent reliable.

Test	Your Results	Normal Range
<b><i>Chemistry Studies:</i></b>		
Glucose:	93	65-109 mg/dL
BUN (Blood Urea Nitrogen):	14	9-27- mg/dL
Creatinine:	0.9	0.5-1.5 mg/dL
BUN/Creat Ratio:	15.6	6-25
Sodium:	139	135-148 mmol/L
Potassium:	4.7	3.5-5.5 mmol/L
Chloride:	102	96-109 mmol/L
Carbon Dioxide:	27	20-32 mmol/L
Calcium:	9.4	8.5-10.6 mg/dL
Total Protein:	7.0	6.0-8.5 g/dL
Albumin:	3.8	3.5-5.5 g/dL
Globulin:	3.2	2.2-4.1 g/dL
Albumin/Globulin Ratio:	1.2	0.9-2.0
Total Bilirubin:	0.4	0.1-1.2 mg/dL
Alkaline Phosphatase	48	25-160 U/L
SGOT (Serum Glutamic Oxaloacetic Transaminase):	15	0-45 U/L
<b><i>Thyroid Studies:</i></b>		
TSH (thyroid stimulating hormone):	1.7	0.4-5.5mlU/L
Uptake (thyroid hormone uptake):	31	24-39%
T4 (thyroxine):	6.0	4.5-12.0 ug/dL
T7 (free thyroxine index):	1.9	1.4-4.9 U

FIG.7V



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**Metabolic and Biochemical Studies continued****Hematology Studies:**

WBC:	9.4	4.0-10.5 $10^3/\mu\text{L}$
RBC:	4.53	4.10-5.60 $10^6/\mu\text{L}$
Hgb:	13.8	12.5-17.0 g/dL
Hct:	41.0	36.0-50.0%
MCV:	91	80-98 fL
MCH:	30.4	27.0-34.0 pg
MCHC:	33.6	32-36 g/dL
Neutrophils:	65	40-74%
Lymphocytes:	27	14-46%
Monocytes:	6	4-13%
Eosinophils:	2	0-7%
Basophils:	0	0-3%
Abslt Cnt: Neutrophil:	6.1	1.8-7.8 $10^3/\mu\text{L}$
Abslt Cnt.: Lymphocyte	2.5	1.0-4.8 $10^3/\mu\text{L}$
Abslt Cnt: Monocyte	0.6	0-0.8 $10^3/\mu\text{L}$
Abslt Cnt: Eosinophil:	0.2	0-0.4 $10^3/\mu\text{L}$
Abslt Cnt: Basophil:	0	0.2- $10^3/\mu\text{L}$
Platelets:	287	140-415 $10^3/\mu\text{L}$

**Lipid Studies:**

Triglycerides:	126	0-199 mg/dL
Total Cholesterol:	196	0-200 mg/dL
HDL	45	35-150 mg/dL
LDL	126	0-130 mg/dL
LDL/HDL Ratio	3.0	1.0-3.6

**Tumor Markers:**

CA 125	25	0-35 IU/mL
CEA:	0.5	0-5.0 ng/mL Smokers 0-3.0 ng/mL Non-Smokers

**Endocrine Studies:**

FSH:	5.3	2.5-10.2 mIU/mL Pre-Menopausal 23.0-116.3 mIU/mL Post-Menopausal
Serum Iron:		40-180 ug/dL
Homocysteine	7	5-15 umol/L Normal Less than 10 umol/L Optimal

**Prostate Specific Antigen:**

PSA:	3.1	0-4 ng/ml
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**Recommendations**

These tests will assist your physician in better understanding your current health status. It is helpful to monitor and track changes over time, so periodic screening is recommended. Any abnormal results should be brought promptly to your physician's attention and reviewed in detail.

FIG. 7W

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## Results Summary:

### Percent of Population at Risk

	<u>Male</u>	<u>Female</u>
Abnormal Arterial Elasticity	54%	49%
Total Cholesterol	59%	57%
HDL	21%	2%
Moderate-Severe Plaque Grade	7%	6%
% Body Fat	88%	45%
BMI	86%	51%

FIG. 8A

# Participation

## Department

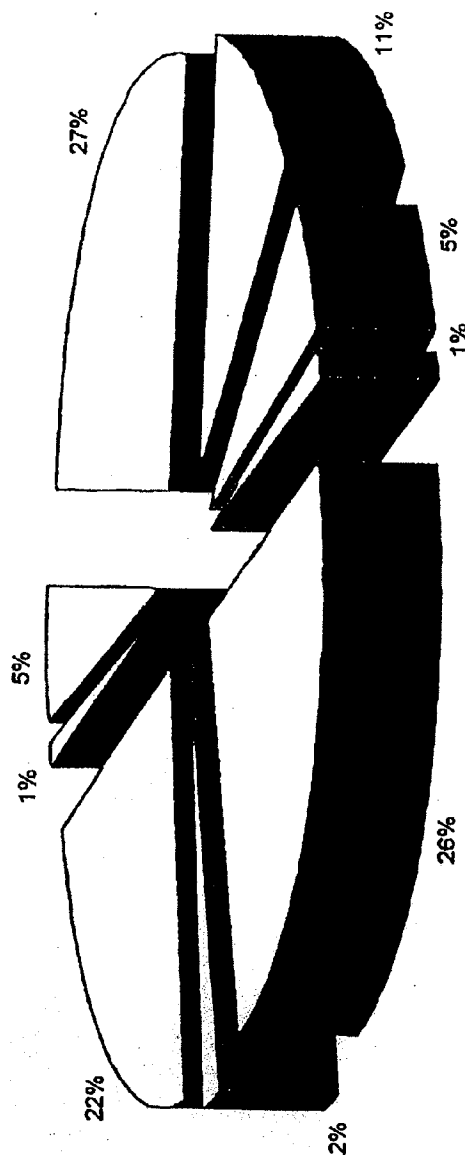
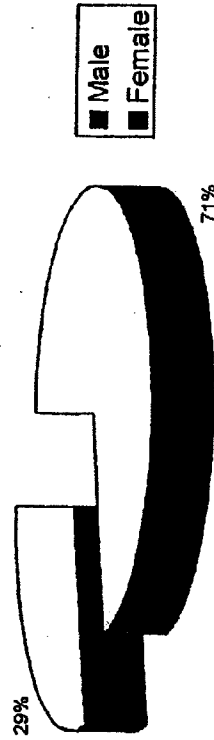


FIG. 8B

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# Participation

Gender



Age Groups

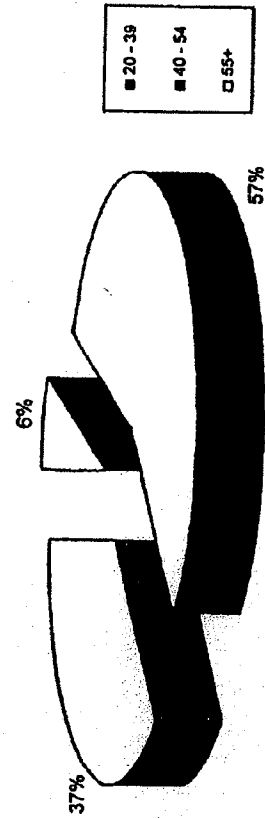
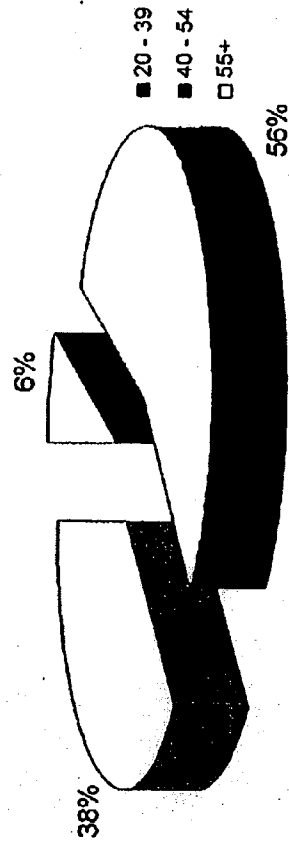


FIG. 8C

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# Participation

Male



Female

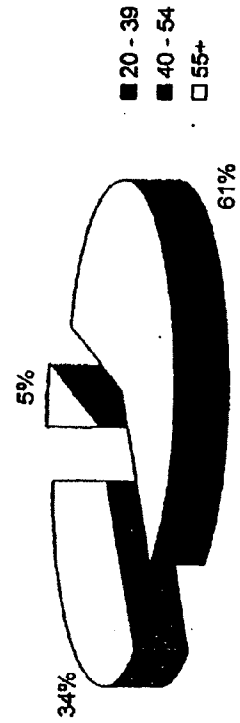


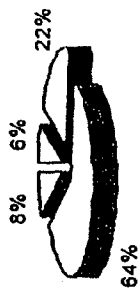
FIG. 8D

# Body Composition

## % Body Fat

Female

- < 19% Below Normal
- 19 - 26% Normal
- > 26% Above Normal
- No test



Male

- < 12% Below Normal
- 12 - 18% Normal
- > 18% Above Normal
- No test



## Body Mass Index

■ Female ■ Male

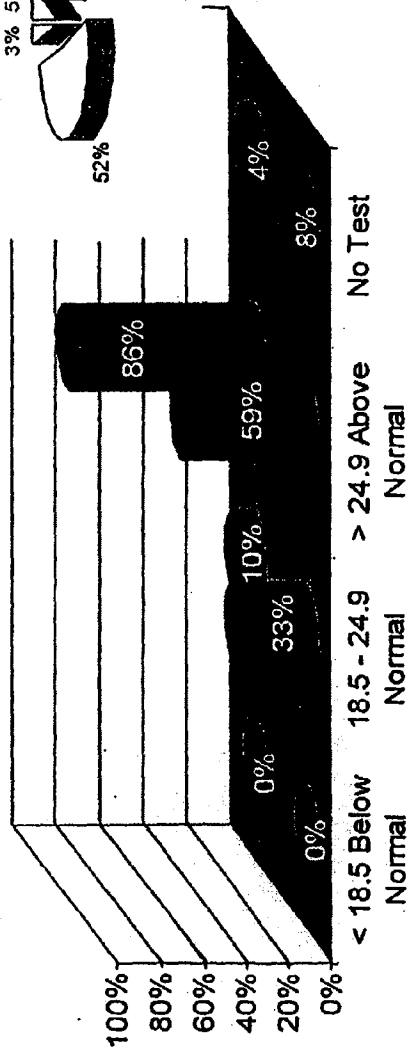
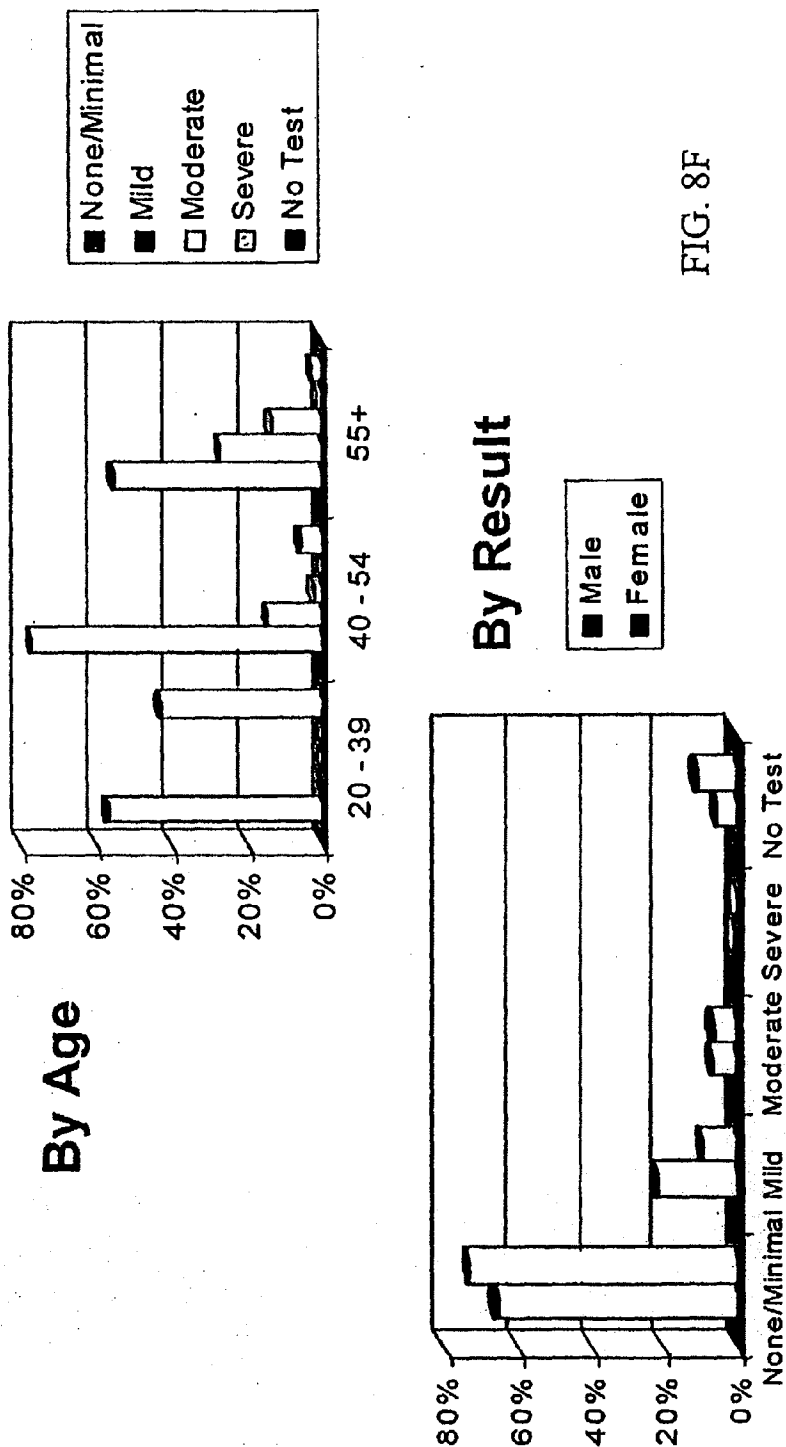


FIG. 8E

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# Carotid Plaque Grades



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# Cholesterol

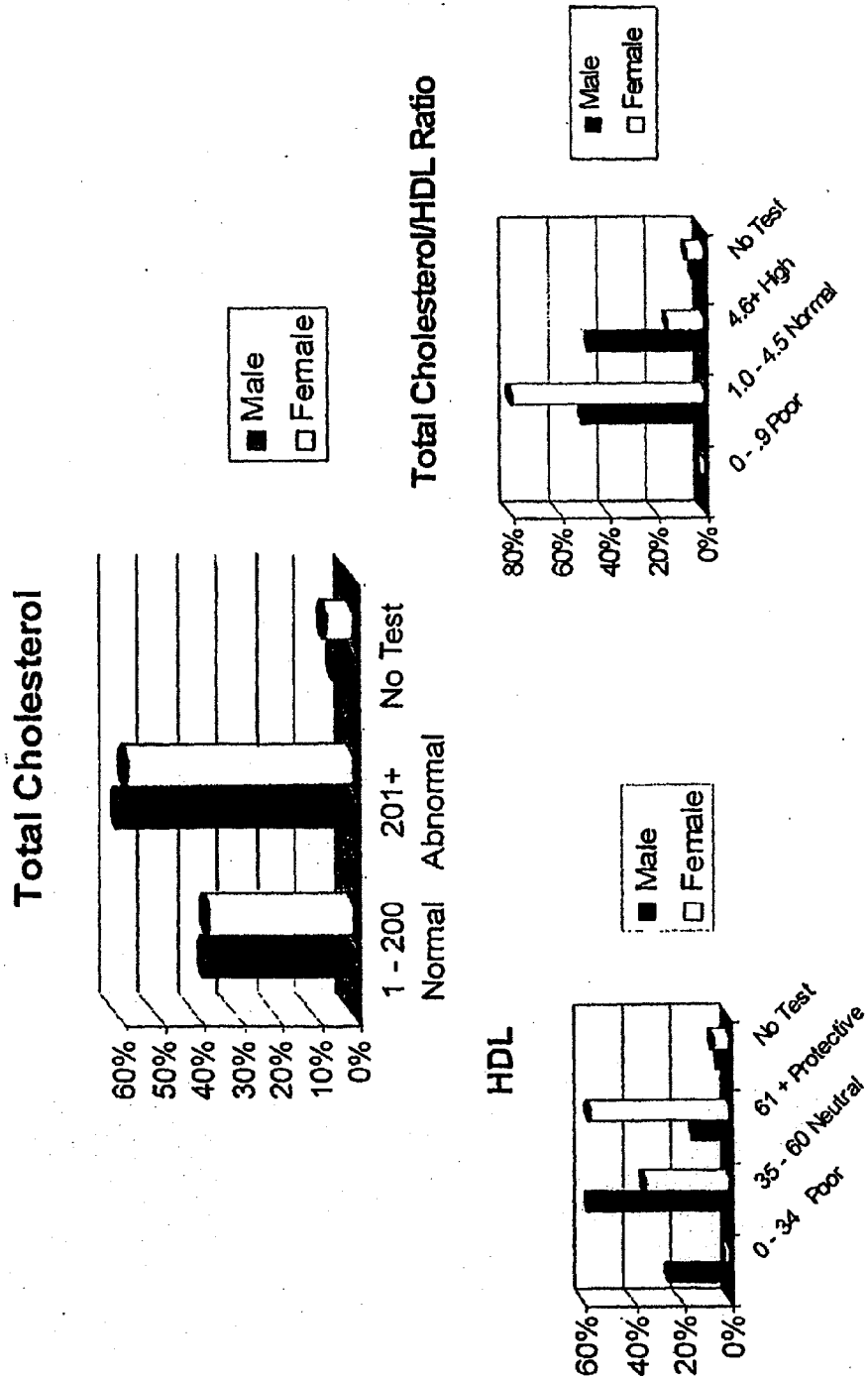


FIG. 8G



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# Arterial Elasticity

## Pulse Pressure

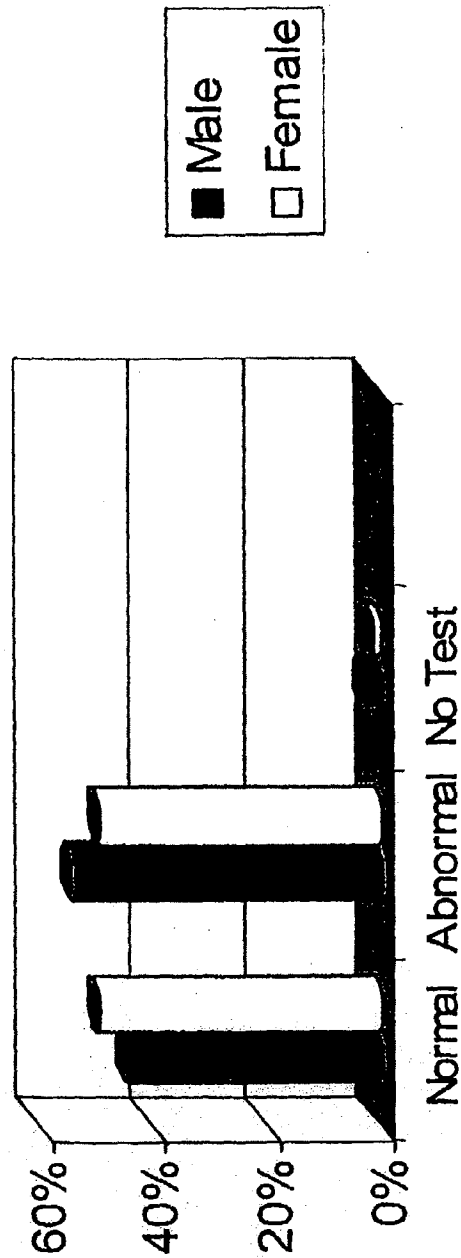
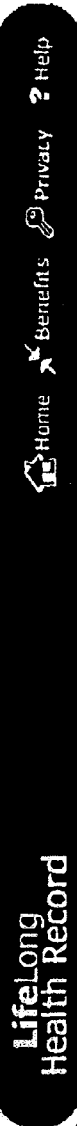


FIG. 8H

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Business Source	No. Of Clients	Forecast Amt.	% Tot Forecast	PreTaxPaid	% Tot Actual	Amt Diff
Billboard	4	\$ 1,783.00	0.83	\$ 2,216.00	0.96	\$ 432.40
Church/Community Center	10	\$ 2,626.00	1.22	\$ 2,774.00	1.21	\$ 148.00
Direct Mail	142	\$ 25,681.40	11.94	\$ 27,063.70	11.76	\$ 1,382.30
Don't Know	6	\$ 66.00	0.03	\$ 1,199.00	0.52	\$ 1,133.00
Friend	156	\$ 23,980.85	11.15	\$ 26,608.00	11.56	\$ 2,627.15
Infomercial	28	\$ 10,347.10	4.81	\$ 11,157.00	4.85	\$ 809.00
Internet	12	\$ 4,461.00	2.07	\$ 5,168.00	2.25	\$ 707.00
Newspaper	225	\$ 73,607.11	34.21	\$ 75,897.80	32.98	\$ 2,290.69
Physician/Healthcare Professional	29	\$ 4,689.80	2.18	\$ 4,785.80	2.07	\$ 69.00
Public Event	243	\$ 9,541.60	4.43	\$ 9,600.50	4.17	\$ 58.90
Radio	10	\$ 858.00	0.40	\$ 862.00	0.37	\$ 4.00
Relative	56	\$ 10,611.70	4.93	\$ 11,062.70	4.81	\$ 451.00
Special Promotion	22	\$ 2,442.20	1.14	\$ 2,476.30	1.08	\$ 34.10
Television	165	\$ 28,788.10	13.38	\$ 31,346.00	13.62	\$ 2,557.90
Workplace	332	\$ 15,682.20	7.29	\$ 17,928.60	7.79	\$ 2,246.40
<b>Grand Total</b>	<b>1,440</b>	<b>\$ 215,166.76</b>	<b>100.00</b>	<b>\$ 230,118.50</b>	<b>100.00</b>	<b>\$ 14,951.76</b>

FIG. 9



It's free. It's easy. When you become a member of HealthScreen America's LifeLong Health Record you will be joining the growing number of people who want to access HealthScreen America's special services to stay informed and manage their health.

Items with a red \* are required for registration.

\*User Name:   
Case sensitive, no special characters (=, \$, @, etc.)

\*Password:   
Case sensitive, no special characters (=, \$, @, etc.)

\*Confirm Password:   
 Password Reminder:

\*Authorization ID:

An Authorization ID is required to view screenings.  
 To receive an Authorization ID, call HealthScreen America's  
 Customer Support at 1-904-877-SCREEN.



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FIG. 10A

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## HEARING

Hearing is important to your general health status. Many daily activities are affected by decreased hearing including conversation, education, speaking on the telephone as well as driving a vehicle. Significant hearing loss may put you at increased risk of social isolation, anxiety and depression.

Your Results	Right Ear:	Left Ear:
1000 Hz:	Pass	Pass
2000 Hz:	Pass	Pass
4000 Hz:	Fail	Fail

The hearing screen is performed by presenting various frequencies to each ear at a loudness of 25 decibels (dB). Each pure tone is tested at 1000Hz, 2000Hz and 4000Hz. You should hear and respond to each separate frequency in order to "pass" that level. The failure to hear and respond will constitute a "fail" *unless you are over age 64.*

For persons aged 65 years and older, a 40-dB tone at 4000 Hz is recommended since high frequency hearing loss is common at this age. If you are over age 64 and hear the 40 dB tone your score will reflect that you "passed". About one in four individuals over age 65 will have some degree of hearing loss; of those with hearing loss, only about 10% who could benefit from a hearing aid actually use one.

A hearing screen can not only identify hearing loss, but also may serve to detect subtle problems that include allergies, eardrum damage and even certain forms of brain tumors.

The loss of hearing often occurs so gradually that you may be unaware of problems. In fact, others are much more likely to first notice it. You should consider a regular assessment of your hearing. If your hearing is not within the normal range, discuss this with your personal physician or a hearing and ear specialist.

Testing Protocol: The test is performed using a Maico MA 27 Audiometer by presenting you with different tones in each ear.  
Reference: Clinician's Handbook of Preventative Services; National Library of Medicine - [www.nlm.nih.gov](http://www.nlm.nih.gov)

FIG. 10B

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## VISION

Many individuals may be unaware of a gradual decrease in their vision. However, more than 90% of adults will eventually benefit from some form of corrective lenses or procedure. The visual acuity test is a useful screen for vision problems and can help determine if correction (with eyeglasses or contacts) or if further evaluation by an ophthalmologist is required. It also can indicate if more serious underlying eye conditions could be present. Some conditions could threaten possible permanent vision loss or even your overall health. In this test your vision is compared to what is typically readable at a distance of twenty feet. The result is expressed as a ratio.

### Your Results

Right: 20/20/25 VA VA  
Left: 20/20/20 VA VA

### Normal Ranges

20/20 VA  
20/20 VA

Loss of vision can be as simple as the need for corrective lenses, or may be due to an underlying medical condition such as diabetes. Common disorders affecting vision include cataracts, macular degeneration, glaucoma, and retinopathy. Poor vision in turn may contribute to accident, falls, isolation or depression.

If your results indicate you have less than normal vision, we recommend you seek further assessment from your doctor or an eye specialist. The American Academy of Ophthalmology recommends a comprehensive eye examination by an ophthalmologist every 1 to 3 years and at least annually for diabetics.

**Testing Protocol:** This test is performed using a CP-2 Everlight Projector Chart by Marco. The client reads projected images, one eye at a time.  
**Reference:** The American Academy of Ophthalmology and Clinician's Handbook of Preventive Services.

FIG. 10C

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**OXYGEN SATURATION**

This machine measures the amount of oxygen present in the bloodstream. Oxygen is required by every cell in the body and affects all chemical reactions that determine good health.

**Your Results**  
Oxygen Saturation: 92 %

Normal Ranges  
Greater than 92%

This test is useful in providing information about problems relating to various types of lung diseases or heart failure.

If your results are abnormal, we recommend you see your physician who may want to conduct further testing such as a chest X-ray, spirometry or a CT scan.

**Testing Protocol:** Using a painless probe on the fingertip, this test is conducted with Welch Allyn technology.

**Reference:** American Lung Association - [www.lungusa.org](http://www.lungusa.org)

**FIG. 10D**

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## URINE ANALYSIS

A urine specimen provides 10 results that are useful in evaluating a variety of conditions. Unfortunately, the urine analysis does not lend itself to a simple explanation. The result of any test alone is less meaningful. If you should have a test result that is outside of the normal range, do not be alarmed. This frequently occurs and may be of little significance. Your body is affected by many factors and your results can be subject to fluctuations and are never 100% accurate.

**Your Results**  
 Specific Gravity: 1.035  
 pH: 8  
 Leukocytes: ++  
 Nitrite: Negative  
 Protein: Trace  
 Glucose: Normal  
 Ketones: +  
 Urobilinogen: ++  
 Bilirubin: Negative  
 Blood: Negative

**Normal Ranges**  
 1.005 - 1.025  
 5 - 8  
 Negative  
 Negative  
 Negative  
 Normal  
 Negative  
 Negative  
 Negative  
 Negative

Abnormal results can provide information to detect conditions such as dehydration, urinary infection or inflammation, kidney stones, or tumors of the kidney or bladder.

If you have an abnormal score, we recommend you provide this information to your physician.

**Testing Protocol:** The client provides a urine specimen at the time of testing, which is analyzed using the Roche Urine Analyzer.  
**Reference:** Manual of Diagnostic and Laboratory Tests. Pagana KD & Pagana TJ 1998.

FIG. 10E

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**CT LUNG SCAN****Low Dose Spiral Lung CT:**

Lung cancer is the most common form of cancer in the world. It also is the leading cause of cancer death for both men and women in America. There will be more than 160,000 new cases of lung cancer diagnosed this year. The vast majority, almost 90%, will be associated with smoking or a history of smoking in the past.

Tragically, the 5-year survival for these individuals diagnosed with lung cancer is only 12 to 14 percent. By the time symptoms appear or the individual feels ill, lung cancer is often far advanced. The diagnosis typically occurs too late for lung cancer to be effectively treated. Yet when detected early (in Stage 1) lung cancer survival rates are dramatically better, as high as 80 to 95 percent (5-year survival).

Early detection strategies are common for cancers of the breast, colon and prostate. Although lung cancer will kill more Americans than all of these types of cancer combined, no early detection strategy for lung cancer is widely utilized. Recent studies have shown that a low dose Spiral CT Lung Scan can detect four times the number of lung cancers as compared to traditional chest x-rays. Moreover, these cancers were six times more likely to be at the earliest stage (Stage 1) when the chances for cure are best. Although this new technique known as spiral or helical low dose CT scanning has been successful in detecting early lung cancers in smokers and former smokers. Whether this will actually save lives has not been proven and studies to answer this important question are in progress.

**You should be aware that the majority of nodules detected by a CT Lung Scan are benign and non-cancerous.** A nodule is especially likely to be benign if it is small (less than 5 mm in size), has smooth edges or has benign calcifications. Many nodules on review by a physician can be immediately be classified as benign and may not require further study. For example, the presence of calcium in a nodule on a high resolution CT can indicate a benign cause such as from an old infection. Even non-calcified nodules most often prove not to be cancer but this will require a physician's prudent judgment to manage these appropriately. Small nodules (less than 5 mm in size) may simply be followed with high resolution CT at 3, 6, 12 and 24 months to ensure that they do not change. The CT Lung Scan may also identify abnormalities of the lung tissue itself known as the lung "parenchyma". Changes in the lung parenchyma may be due to a variety of medical conditions such as emphysema or asthma.

Your personal physician can use the information gathered by a low dose CT Lung Scan to follow any abnormalities and take timely action when needed. One should utilize that the best preventive measure is to not smoke or to quit as soon as possible. Also, no test can substitute the expert advice of your physician. It is the need for a careful examination and

**Testing Protocol:** The CT Lung Scan was performed on a GE helical high speed computed tomography scanner. A low dose lung protocol examines 10 millimeter sections through the lung fields. A registered radiologist conducts the procedure. A radiologist reviews your CT images and the interpretation will be forwarded by mail. The radiologist is a highly trained physician who specializes in the interpretation of radiologic studies such as this one.

The low dose CT Lung Scan at HealthScreen America is painless, safe, rapid and cost effective. The actual procedure requires only 15 to 30 seconds and is a fraction of the cost of a traditional CT scan. The exam's x-ray exposure of only about that of two routine chest x-rays. Finally, there is no need to disrobe and no risk from medications or from intravenous contrast or needles. Findings from baseline screenings. *Lancet* 1999;354:99-105. American Cancer Society - [www.cancer.org](http://www.cancer.org)

**FIG. 10F**



## HEART CT SCAN

### CT Heart Scan:

Coronary heart disease is the number one cause of death for both men and women in the United States. Millions of Americans have heart disease and don't know it. For many of these individuals the first and the last symptom they will experience will be death.

The hallmark of heart disease is the presence of plaque within the heart's arteries known as the "coronaries." The coronary arteries supply blood and oxygen to the heart itself. Plaque can build within these arteries when they are damaged by various factors such as high cholesterol, high blood pressure, diabetes or smoking. This process of plaque formation involves the deposition of fatty substances onto the arterial wall and is called "atherosclerosis".

As plaque builds up, it begins to harden and its calcium content gradually increases. Normal coronary arteries do not contain significant calcium, however those with hard and calcified plaque will have large amounts of extra calcium. Fortunately, the advanced helical CT Heart Scan is highly sensitive at detecting and measuring calcium and hard plaque within the heart arteries. It provides a "calcification" score that can help you and your physician predict possible future heart problems. The CT Heart Scan cardiac calcification score affords physicians the opportunity to detect atherosclerosis years before symptoms develop. Aggressive preventative measures then can be used to halt or even reverse atherosclerotic disease.

Normal Range	0	Risk of CVD* is less than 5%
	Low: 1-10	Risk of CVD* is less than 10%
	Mild: 11-100	Moderate risk, at least mild plaque burden
	Mod: 101-400	Moderate-High risk, at least moderate plaque burden
	Severe: Greater than 400	High risk of significant CVD*

\*CVD - Cardiovascular Disease

The cardiac calcification score has been shown to be an independent predictor of future cardiovascular events such as heart attack and stroke. It can identify an individual who has evidence of atherosclerotic disease. However, it is important to note that many cardiac tests such as a treadmill test only identify "obstructive" lesions. Obstruction of blood flow typically occurs when the artery is at least 70 percent blocked. Thus, many individuals with this disease are told they are "normal" when less than this level of blockage exists. Unfortunately, this only allows physicians to react to obstructive disease rather than preventing blockage from developing in the first place.

There are several factors known to increase the risk of coronary heart disease. These include high total cholesterol, high LDL, elevated triglycerides, low HDL, smoking, diabetes, high blood pressure, obesity, or a sedentary lifestyle. Yet having one of these risk factors does not guarantee the presence of heart disease. On the other hand, many individuals who die of coronary heart disease have none of these recognized risk factors.

The CT Heart Scan cardiac calcification score provides a non-invasive method of assessing atherosclerosis (or hardening of the arteries) in the heart arteries. It should be noted that this technology can not measure the amount of "soft plaque" in the arteries, which often is responsible for sudden, fatal heart attacks. With time, "soft plaque" becomes hard calcified plaque. Often people who have "hard plaque" also tend to have more of the "soft plaque." Thus, the cardiac calcium score is helpful in predicting the likelihood of future events such as heart attack or cardiac death.

Males over the age of 35 and females over the age of 40 with known risk factors or a family history of heart disease are the best candidates for a CT Heart Scan. The information gathered by the scan may change an individual's risk category in treatment guidelines, thus encouraging your physician to institute more aggressive prevention strategies.

FIG. 10G

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**HEART CT SCAN cont.****How Do You Compare?****Findings from Measuring Cardiac Calcification Scores  
in 13,973 Men and 5,227 Women with No Symptoms****Men (13,973)**

Percentile	Age						
	40 - 45	46 - 50	51 - 55	56 - 60	61 - 65	66 - 70	70 +
10th	0	0	0	1	1	3	3
25th	0.5	1	2	5	12	30	65
50th	2	3	15	54	117	166	350
75th	11	36	110	229	386	538	844

**Women (5,227)**

Percentile	Age						
	40 - 45	46 - 50	51 - 55	56 - 60	61 - 65	66 - 70	70 +
10th	0	0	0	0	0	0	0
25th	0.1	0.1	0.1	0.2	0.5	1	4
50th	0.1	0.1	1	1	3	25	51
75th	1	2	6	22	68	148	231

Reference: Janowitz WR, Agatston AS, Kaplan G, Vliemont M Jr. "Differences in Prevalence and Extent of Coronary Artery Calcium Detected by Ultrafast Computed Tomography in Asymptomatic Men and Women". *American Journal of Cardiology*, 1993;72:247-254.

It is important to note that a cardiac calcification score must be integrated into an individual's overall risk profile. Although the medical professionals at HealthScreen America can explain how your results compare to an average individual, your personal physician should guide your health management decisions.

If an elevated calcification score is found, then more aggressive therapy or further testing may be warranted. If calcium is not detected in the coronary circulation, this does not rule out the presence of atherosclerosis in the form of "soft plaque." However, a lack of calcium does imply a very low likelihood of significant obstruction.

For these reasons, the CT Heart Scan results should be used in tandem with other screening tests at HealthScreen America to identify the physical presence of abnormalities. Your physician will take each piece of information into consideration as "clues" when solving the overall "puzzle" of your health status.

**Testing Protocol:** Computed tomography of the heart is a simple, painless and rapid examination. There is no need to disrobe and no risk from medications, intravenous contrast or needles. The procedure takes a matter of minutes during which you lie on an open table-like platform. You should avoid caffeine, colas, coffee, nicotine, stimulants, decongestants or weight loss products in the four hours prior to your exam since a rapid pulse may interfere with the exam.

The scan uses ECG gating and an individual holding his breath to minimize motion. It produces approximately 40 images of the heart for the purposes of coronary artery calcium scoring. Post processing is performed on a 3 dimensional computer workstation to obtain the resting heart images, select areas of interest, determine the calcium score for each coronary artery and provide an assessment of the extent of atherosclerotic disease. Registered radiologic technologists conduct all examinations and board certified radiologists review all calcification scores.

Since the examination involves exposure to potentially harmful radiation, your informed consent is required. However, the level of radiation exposure is low. It is only about one third of that of an average coronary angiogram. Shielding of sensitive areas is typically not necessary, but is available upon request.

Reference: Rumberger JA, et al. Electron Beam Computed Tomographic Coronary Calcium Scanning: A Review and Guidelines for use in Asymptomatic Persons *Mayo Clinic Proceedings* 1999;74:243-252. Maher JE, et al. Progression of Coronary Artery Calcification. *Mayo Clinic Proceedings* 1999;74:347-355; American Heart Association - [americanheart.org](http://americanheart.org)

**FIG. 10H****SUBSTITUTE SHEET (RULE 26)**

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Screening Date: 01/21/00  
Client Information: John Doe  
Date of Birth: 01/01/1955

**CT Heart Scan****Technique for Physicians:**

A high-speed spiral CT of the heart is performed with EKG gating and suspended respiration. The examination is administered by registered radiologic technologists and board certified physicians review calcification scores. Scoring is performed using the Agatston method. Areas of the mediastinum, lungs, spine and abdomen are not adequately imaged and were not assessed in this study.

**Coronary Arteries:**

Your Results: 363

CORONARY	SCORE
Left Main Artery (LMA)	0
Left Anterior Descending (LAD)	358
Left Circumflex (LCX)	5
Right Coronary Artery (RCA)	0
Posterior Descending Artery (PDA)	0
Total CAC Score	363

If your score is 0: Absent calcium was not detected in the arteries of the heart. This does not absolutely exclude the presence of plaque. Non-calcified or "soft plaque" may be present and is not detected by this study. Your score does imply a very low likelihood of significant blockage within the coronary arteries.

**Risk Assessment:** There is a very low risk of cardiovascular disease. The probability of significant coronary heart disease is estimated to be less than 5% based on this cardiac calcification study.

**Recommendations:**

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.

If your score is 1 - 10: Calcium was detected with the coronary circulation and confirms the presence of at least mild atherosclerotic plaque. Non-calcified or "soft plaque" may also be present and is not detected by this study. The degree of cardiac calcification implies a low likelihood of significant obstructive lesions within the coronary arteries.

**Risk Assessment:** There is a low risk from cardiovascular disease based on this study. The probability of significant coronary heart disease is estimated to be less than 10% based on this cardiac calcification score.

**Recommendations:**

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.
2. Evaluation and control of modifiable risk factors is warranted.
3. Review this and all results with your primary care physician.

FIG. 10I

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Screening Date: 01/21/00  
Client Information: John Doe  
Date of Birth: 01/01/1955

**If your score is 11–100:** Moderate calcium was detected and confirms the presence of moderate plaque. Non-calcified or “soft plaque” may also be present and is not detected by this study. The degree of cardiac calcification implies an increased risk for the development of significant lesions within the coronary arteries.

**Risk Assessment:** There is a moderate risk from cardiovascular disease based on this study. There is definite and at least mild plaque present within the coronary arteries based on this cardiac calcification study.

**Recommendations:**

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.
2. Evaluation and control of modifiable risk factors is warranted.
3. Your physician may consider primary prevention guidelines for cholesterol management and aspirin therapy.
4. Review this and all results with your primary care physician.

**If your score is 101 – 400:** High calcium was detected in the arteries of the heart and confirms the presence of a moderate to high degree of plaque. Non-calcified or “soft plaque” may also be present and is not detected by this study. The degree of cardiac calcification implies a definite increased risk for significant obstructive lesions within the coronary arteries.

**Risk Assessment:** There exists a moderate to high risk from cardiovascular disease based on this study. There is definite and moderate to high grade plaque present within the coronary arteries based on this cardiac calcification study.

**Recommendations:**

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.
2. Evaluation and control of modifiable risk factors is warranted.
3. Your physician may consider secondary prevention guidelines for cholesterol management and aspirin therapy.
4. Your physician may consider further testing to exclude silent ischemia.
5. Review this and all results with your primary care physician.
6. If you do not have a physician, we will work with you to find one.

**If your score is greater than 400:** Extensive calcium was detected with the coronary circulation and confirms the presence of an extensive degree of plaque. Non-calcified or “soft plaque” may also be present and is not detected by this study. The degree of cardiac calcification implies a definite risk of significant lesions within the coronary arteries. Extensive calcifications are often seen in individuals with an established history of heart disease.

**Risk Assessment:** There exists a high risk from cardiovascular disease based on this study. Definite and extensive plaque is present within the coronary arteries. There is a high likelihood (greater than 90%) of at least one significant obstructive lesion based on this study.

**Recommendations:**

1. Healthy lifestyle maintenance is appropriate. This includes a balanced, low fat diet, not smoking, and regular exercise under your physician's guidance.
2. Evaluation and control of modifiable risk factors is warranted.
3. Your physician may consider secondary prevention guidelines for cholesterol management and aspirin therapy.
4. Your physician may consider further stress testing to exclude silent ischemia.
5. Review this and all results with your primary care physician.
6. If you do not have a physician we will work with you to find one.
7. Consultation with a cardiologist also may be prudent.

FIG.10J

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/06089A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 G06F19/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, EPO-Internal, PAJ, INSPEC, BIOSIS, COMPENDEX

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	HEALTHSCREEN INTERNATIONAL INC.: "Healthscreenamerica.com announces "bricks and Mortar" addition" PRESS RELEASE, 'Online! 22 December 1999 (1999-12-22), XP002196378 Retrieved from the Internet: <URL:http://www.healthscreenamerica.com/AboutUs/PressReleases/ViewPress.asp?xmlfile=../xml/PR9912BricksAndMortar.xml> 'retrieved on 2002-04-16! the whole document	1-27
X	US 5 940 802 A (FRANSEN STEPHEN R ET AL) 17 August 1999 (1999-08-17) column 1, line 14 - line 23 column 5, line 10 -column 6, line 14 column 7, line 58 -column 8, line 20 --- -/--	1-27

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

19 Apr11 2002

Date of mailing of the international search report

07/05/2002

Name and mailing address of the ISA

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Authorized officer

Muñoz, M

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 01/06089

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 958 778 A (KYOTO DAIICHI KAGAKU KK) 24 November 1999 (1999-11-24) paragraph '0001! paragraph '0006! - paragraph '0010! paragraphs '0026!-'0033! ---	1-27
E	WO 01 29688 A (HANLON TERRENCE J O ;OSTERER MICHAEL F (US); BANDES ALAN S (US); G) 26 April 2001 (2001-04-26)  page 9, line 2 - line 26 page 13, line 3 - line 9 figure 1 claims -----	1-3, 5-12, 15-17, 21-27

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No  
PCT/US 01/06089

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5940802	A	17-08-1999	NONE	
EP 0958778	A	24-11-1999	JP 10028678 A	03-02-1998
			JP 10124601 A	15-05-1998
			JP 10248817 A	22-09-1998
			EP 0958778 A1	24-11-1999
			US 6221009 B1	24-04-2001
			WO 9802086 A1	22-01-1998
			US 2001009972 A1	26-07-2001
WO 0129688	A	26-04-2001	AU 1336401 A	30-04-2001
			WO 0129688 A1	26-04-2001